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Summary Report on Issues in Ecological Risk Assessment

Eastern Research Group, Inc., Arlington, MA

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In 1986, the U.S. Environmental Protection Agency (EPA) published a series of guidelines for carrying out human health risk assessments. As part of the ongoing effort to develop guidance in areas not addressed by the 1986 guidelines, EPA's Risk Assessment Forum sponsored a series of meetings to consider issues relevant to developing the Agency's first Agency-wide guidelines for ecological risk assessment.

This report summarizes the discussion and conclusions of seven information-gathering meetings held in the spring of 1990. Invited speakers and EPA staff addressed the scope and content of future ecological guidelines, the nature and diversity of ecological assessments, approaches to characterizing and quantifying uncertainty in ecological hazard and exposure assessments, and the potential use of population modeling for characterizing ecological risk.

Relying in part upon the results of these discussions, EPA has embarked on a multiyear effort to develop ecological risk assessment guidelines that will foster consistency in the Agency's approach to evaluating not only the risks posed by conventional stresses such as toxic chemicals, but also other anthropogenic stresses such as habitat loss and global climate change.

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ON ISSUES IN
ECOLOGICAL RISK ASSESSMENT

Assembled by:

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PREFACE

The U.S. Environmental Protection Agency's Risk Assessment Forum (Forum) is responsible for developing Agency-wide risk assessment guidelines. As part of this ongoing effort, EPA's Risk Assessment Council asked the Forum to organize a program to develop ecological risk assessment guidelines for Agency-wide use. During the spring of 1990, the Forum invited experts from the scientific community and other federal and state agencies to participate in a series of scientific "colloquia" and informational meetings to discuss issues central to the future development of ecological risk assessment guidelines.

Risk Assessment Forum colloquia are informal meetings at which EPA scientists discuss current issues and exchange information on risk assessment topics. The Forum does not expect issues to be resolved through this format; rather, the Forum seeks to initiate a dialogue to sharpen the issues, prompt additional study, and suggest an outline for further work. The four colloquia summarized here accomplished these objectives. In addition, three coordination meetings added the perspectives of EPA's Science Advisory Board and scientists from other regulatory agencies to the dialogue. These seven meetings, together with discussions begun under the auspices of the Risk Assessment Council, are providing the basis for work on ecological risk assessment guidelines.

This report summarizes the discussions at those meetings, and identifies key points to be considered by those drafting the future guidelines. This document reflects the opinions of meeting participants; it does not encompass all scientific opinion on the issues, nor does it express an Agency preference, position, or policy on any of the issues discussed.

The authors gratefully acknowledge the assistance of the following EPA scientists in organizing and chairing the sessions: Edward Bender, Steve Bradbury, Michael Brody, Lawrence Burns, Patricia Cirone, Suzanne Marcy, David Mauriello, Susan Norton, Anne Sergeant, Michael Slimak, Gerald Stober, and Molly Whitworth.

The authors also appreciate the helpful suggestions of the many scientists who contributed to these discussions. Their names are listed in the meeting minutes.

ABSTRACT

In 1986, the U.S. Environmental Protection Agency (EPA) published a series of guidelines for carrying out human health risk assessments. As part of the ongoing effort to develop guidance in areas not addressed by the 1986 guidelines, EPA's Risk Assessment Forum sponsored a series of meetings to consider issues relevant to developing the Agency's first Agency-wide guidelines for ecological risk assessment.

This report summarizes the discussions and conclusions of seven information-gathering meetings held in the spring of 1990. Invited speakers and EPA staff addressed the scope and content of future ecological guidelines, the nature and diversity of ecological assessments, approaches to characterizing and quantifying uncertainty in ecological hazard and exposure assessments, and the potential use of population modeling for characterizing ecological risk.

Relying in part upon the results of these discussions, EPA has embarked on a multiyear effort to develop ecological risk assessment guidelines that will foster consistency in the Agency's approach to evaluating not only the risks posed by conventional stresses such as toxic chemicals, but also other anthropogenic stresses such as habitat loss and global climate change.

AUTHORS, CONTRIBUTORS, AND REVIEWERS

EPA's Risk Assessment Forum (Forum) sponsored the meetings summarized in this report. Members of the Forum's Ecological Risk Oversight Group assisted in planning discussion topics. Forum staff provided overall direction and coordination and prepared this document. Eastern Research Group, Inc. (EPA Contract No. 68-C8-0036) prepared minutes of the various meetings (included as appendices to this report), and provided assistance for this report.

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EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) is presently developing guidelines for conducting ecological risk assessments. This is a challenging task. Ecological risk assessment involves multiple endpoints at different levels of biological organization, from single species to communities of organisms to entire ecosystems. There are also many different types of ecological assessments, ranging from predictive evaluations of the potential effects posed by new chemicals to retrospective analyses and monitoring studies that attempt to determine the cause of observed effects. In view of the complex nature of this subject, and to provide a basis for planning ecological risk assessment guidelines, the EPA Risk Assessment Forum sponsored a series of "colloquia" to discuss technical issues, as well as several coordination meetings with state agencies, other federal agencies, and EPA's Science Advisory Board (SAB).

EPA scientists and experts in ecology and ecological risk assessment met and exchanged views on many issues that will impact guidelines development. Topics discussed included selection of an appropriate ecological risk assessment paradigm, uncertainty issues in hazard and exposure assessment, and population modeling. Representatives from state and federal agencies described methods for ecological risk assessments used in their organizations, and the SAB provided an informal consultation on the development of the guidelines. Major points from these discussions are summarized below.

- Risk Assessment Paradigm. EPA currently uses the paradigm proposed by the National Academy of Sciences to conduct human health assessments. This paradigm, or procedural framework, can serve as a starting point for developing an ecological risk assessment paradigm, but may need modification to account for differences in principles and methods used for human health and ecological effects assessment. In addition, the ecological risk assessment guidelines may involve more than one paradigm to incorporate the range of biological, temporal, and spatial scales involved in ecological assessments and the potential complex interactions between multiple anthropogenic (chemical and nonchemical) and natural stresses. Ecological risk assessments that are predictive in nature, such as those for new chemicals, also may call for a different approach than ecological assessments that attempt to determine retrospectively whether impacts have occurred as a result of previous actions.

- Endpoint Selection. Colloquium participants generally agreed that the complexity of ecological systems requires a unique approach for identifying endpoints for ecological assessments. The identification of both assessment endpoints (impacts of interest) and measurement endpoints (parameters to be measured) is best done at the initial stages of a risk assessment. It would be useful to review and compare the concepts and terminology associated with ecological and human health assessments so that regulators can develop appropriate expressions of the ecological values to be protected and assessors can properly characterize ecological risk.

- Uncertainties. A critical component of the ecological risk assessment process is determining the nature of the uncertainties associated with ecological effects assessment methodologies. Sources of uncertainty include extrapolations among species, between different levels of biological organization, and from laboratory test results to field situations. Colloquium discussions indicated that extrapolation models and toxicity data bases are generally better developed for marine and freshwater organisms than for avian and other terrestrial species.

- Exposure Assessment. Exposure assessment provides estimates of the magnitude, frequency, and duration of contact with one or more stresses in the environment and is a fundamental part of the risk assessment process. No single expression of exposure is applicable to all ecological risk assessments. Many factors can contribute to uncertainties in exposure assessment, such as limited knowledge of the populations at risk, factors controlling contaminant bioavailability, and difficulties in extrapolating from the laboratory to the field and over different spatial and temporal scales. Uncertainties may also result from our limited ability to evaluate time-variable single- and multiple-stress exposures and lack of knowledge regarding the resiliency and recovery potential of stressed ecosystems.

- Population Modeling. The use of population modeling in ecological risk assessments was discussed, and several models were described that use existing data to project and infer (but not to predict or forecast) effects on demographic properties at the population level. Colloquium participants reviewed many types of models, including matrix models, perturbation and sensitivity analyses, fisheries stock-recruitment models, empirical time-series models, and spatial models. In spite of their limited utility for some applications, such as projecting species-specific impacts in field situations, modeling techniques can provide an ecological framework for interpreting toxicity data and testing hypotheses, a technical basis for decision making, and a mechanism for examining alternative management strategies.

- Future Guidelines. Participants from state and federal agencies described many different approaches to ecological assessments, including predictive hazard assessments, retrospective impact assessments, and monitoring studies. It was apparent that many state and federal agencies currently conduct ecological assessments and use these assessments as a basis for decisions. Participants generally agreed that EPA should begin the guidelines development process with a broad outline describing the basic principles involved, followed by a set of more detailed and specific guidelines.

Relying in part upon information and advice gathered during the colloquia and meetings, EPA has initiated a three-part program to develop ecological risk assessment guidelines. During 1991, EPA will prepare a "framework" document that sets forth general concepts and principles, several site-specific case studies illustrating the state-of-the-practice in ecological risk assessment, and a planning report that outlines specific areas to be covered in future guidelines. Then, over the next few years, EPA expects to draw on these materials to propose and issue specific guidelines for ecological risk assessment. Additional information on these activities will appear in the *Federal Register* in 1991.

SECTION ONE

INTRODUCTION

1.1 BACKGROUND

In 1983, the National Academy of Sciences (NAS) published *Risk Assessment in the Federal Government: Managing the Process* (National Research Council [NRC], 1983). In that report, NAS recommended that federal agencies establish "inference guidelines" for risk assessments. In response, the U.S. Environmental Protection Agency (EPA) greatly intensified work on guidelines for human health and exposure assessment. As a result, in 1986 EPA published risk assessment guidelines (U.S. EPA, 1986a-e) addressing the following topics:

- Carcinogen risk assessment
- Mutagenicity risk assessment
- Health risk assessment for chemical mixtures
- Health assessment of suspect developmental toxicants
- Exposure assessment

Since 1986, EPA has proposed additional human health guidelines (U.S. EPA, 1988a, b, c) and changes related to the 1986 guidelines (U.S. EPA, 1989). EPA is initiating a similar effort to produce the ecological risk assessment guidelines needed to guide the many types of ecological risk assessments used as part of regulatory decision making.

Creation of ecological risk assessment guidelines is a challenging task. At least 10 years of guidance development and consensus building preceded the 1986 publication of the Agency's first full set of health risk assessment guidelines; ecological risk assessment has not yet reached that stage of development. In addition, while human health assessment focuses on a single species (humans), ecological risk assessment involves multiple endpoints at different levels of biological organization, from single species to communities of organisms to entire ecosystems. There are also many different types of ecological assessments, ranging from predictive evaluations of the potential effects posed by new chemicals and complex mixtures to retrospective analyses and monitoring studies that examine the interactions of multiple anthropogenic and natural stresses in an effort to determine the cause of observed effects. It is important that future ecological risk assessment guidelines address EPA's traditional regulatory concerns as well as existing and emerging problems of nonchemical stresses operating at regional and global scales.

1.2 COLLOQUIUM AND MEETING SERIES

To help clarify the many issues related to developing ecological risk assessment guidelines, EPA's Risk Assessment Forum (Forum) sponsored a series of information-gathering colloquia from March to July 1990. The Forum, which is made up of 18 senior EPA scientists representing various scientific disciplines involved in the risk assessment process, is responsible for developing consensus risk assessment guidelines for human health, exposure, and ecological effects. The colloquia sponsored by the Forum brought together experts in ecological risk assessment to discuss the following topics:

- Applicability of the NAS Paradigm. In 1983 NAS developed a paradigm that EPA has used for many years to assess risk for cancer and other adverse effects on humans. The scheme consists of four processes: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Attendees at the first colloquium discussed how best to present the elements of an ecological risk assessment, using the NAS paradigm as a starting point.

- Uncertainty Issues in Hazard Assessment. The second colloquium focused on the sources and methods for estimating uncertainties in the use of toxicity and other response data for ecological risk assessments. Participants discussed the types of methods and magnitudes of the uncertainties encountered in extrapolating from species to species, from laboratory conditions to field conditions, from one exposure duration to another (e.g., acute to chronic), and from one endpoint to another (e.g., LC_{50} to lowest-observed-effect level).

- Uncertainty Issues in Exposure Assessment. Using examples from both aquatic and terrestrial systems, many aspects of exposure assessment were addressed in the third colloquium, including the routes and extent of exposure, uncertainties in determining exposures, multiple exposures, and ecosystems' responses to and recovery from exposure.

- Population Modeling. In the fourth colloquium, invited scientists described methods for modeling the responses of populations of organisms to stress, and discussed the use of these models in characterizing ecological risk.

In addition to the colloquia, the Forum held coordination meetings with representatives of state and federal agencies, and EPA's Science Advisory Board (SAB) provided an informal consultation.

- Meeting with State Representatives. Representatives from a number of state environmental agencies provided examples of ecological risk assessment. Issues discussed included the use of the NAS risk assessment paradigm, methods for hazard and exposure assessment, choices regarding monitoring endpoints, and characterizations of uncertainty.

- Meeting with Federal Representatives. Representatives from several federal agencies described how ecological risk assessment is used within their organizations. This group discussed issues similar to those reviewed by the state agency representatives.

- SAB Meeting. The Ecological Risk Consultative Group, a subcommittee of SAB's Ecological Processes and Effects Committee, informally reviewed the status of the development of ecological risk assessment guidelines at EPA. The group provided recommendations concerning EPA's approach in developing these guidelines.

This report identifies major points brought out in the discussions, and draws conclusions relevant to the development of the ecological risk assessment guidelines at EPA. Included in the appendices are the agenda, list of invited participants and speakers, and minutes for each meeting.

1.3 REFERENCES

National Research Council. 1983. Risk assessment in the federal government: managing the process. Washington, DC: National Academy Press.

U.S. Environmental Protection Agency. 1986a. Guidelines for Carcinogen Risk Assessment. Fed. Reg. 51:33992-34003. September 24.

U.S. Environmental Protection Agency. 1986b. Guidelines for Mutagenicity Risk Assessment. Fed. Reg. 51:34006-34012. September 24.

U.S. Environmental Protection Agency. 1986c. Guidelines for the Health Risk Assessment of Chemical Mixtures. Fed. Reg. 51:34014-34025. September 24.

U.S. Environmental Protection Agency. 1986d. Guidelines for the Health Assessment of Suspect Developmental Toxicants. Fed. Reg. 51:34028-34040. September 24.

U.S. Environmental Protection Agency. 1986e. Guidelines for Estimating Exposure. Fed. Reg. 51:34042-34054. September 24.

U.S. Environmental Protection Agency. 1988a. Proposed Guidelines for Assessing Male Reproductive Risk and Request for Comments. Fed. Reg. 53:24850-24869. June 30.

U.S. Environmental Protection Agency. 1988b. Proposed Guidelines for Assessing Female Reproductive Risk; Notice. Fed. Reg. 53:24834-24847. June 30.

U.S. Environmental Protection Agency. 1988c. Proposed Guidelines for Exposure-Related Measurements and Request for Comments; Notice. Fed. Reg. 53:48830-48853. December 2.

U.S. Environmental Protection Agency. 1989. Proposed Amendments to the Guidelines for the Health Assessment of Suspect Developmental Toxicants; Request for Comments; Notice. Fed. Reg. 54:9386-9403. March 6.

SECTION TWO
COLLOQUIUM SYNOPSES

2.1 PARADIGM SELECTION

2.1.1 The NAS Paradigm

The basic paradigm now used for human health risk assessments within EPA is based largely upon the 1983 NAS publication entitled *Risk Assessment in the Federal Government: Managing the Process* (NRC, 1983). The risk assessment paradigm, as defined by NAS, includes the processes of hazard identification, dose-response assessment, exposure assessment, and risk characterization. The interrelationship of these processes is shown in Figure 2-1 (NRC, 1983); EPA's 1986 risk assessment guidelines for health and exposure assessment follow this paradigm (U.S. EPA, 1986a-e).

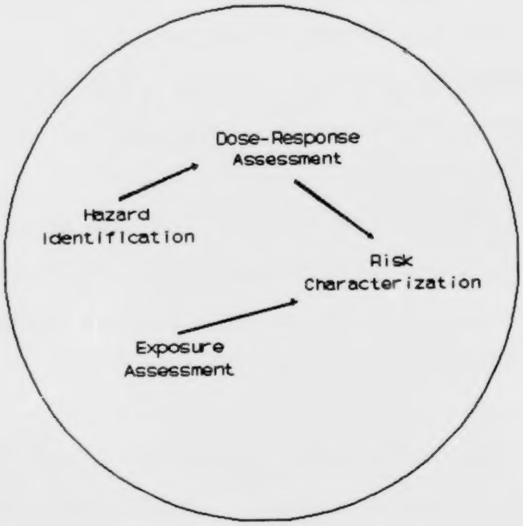
Dose-Response Assessment
Hazard Identification
Risk Characterization
Exposure Assessment

Figure 2-1. The four components of risk assessment and their relationship according to the NAS paradigm.

2.1.2 Relationship of Ecological Risk Assessment to the NAS Paradigm

Although there has been increasing use of variations of the NAS paradigm to address ecological issues, the terminology is not well standardized. To prevent confusion and misunderstandings, it is important that standard terminology for ecological risk assessment be developed. *Ecological risk assessment*, as defined by the Society of Environmental Toxicology and Chemistry (SETAC, 1987), is ". . . the process of assigning magnitudes and probabilities to an adverse effect resulting from human activities or natural catastrophes."[1] The term *hazard assessment* has been applied to at least two definitions. According to SETAC (1987), hazard assessment involves calculating "a quotient or margin of safety by comparing the toxicological endpoint of interest (usually an estimate of the safe concentration) to an estimate of exposure concentration. A judgment is then made on the adequacy of the margin of safety." Others define hazard assessment as the determination of the adverse effect of a chemical or nonchemical stress. This latter, more restrictive definition is used in this report.

Ecological risk assessment may be distinguished from hazard assessment in that "risk assessment employs scientific methods to estimate probabilities of clearly prescribed effects. Hazard assessments have relied more on margin of safety and the expert judgment of the assessor than on formal techniques, such as mathematical and statistical models, which define the magnitude of uncertainty in the effects and exposure estimates" (SETAC, 1987). While both hazard and risk assessment involve the integration of exposure and effects assessments, risk assessment also contains estimates of the probabilities of adverse effects. This distinction between hazard and risk frequently is not recognized and as a result the term ecological risk assessment often is used very broadly to refer to any process that determines potential adverse ecological effects resulting from human activities.

While participants in the first colloquium generally agreed that it is possible to use a modified version of the NAS paradigm as a basis for ecological risk assessment, a number of significant differences were noted between the approaches used for human health and ecological risk assessments. These differences are detailed in Sections 2.1.2.1 through 2.1.2.4.

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[1] The NAS definition of risk assessment (NRC, 1983) is broader in scope, i.e., risk assessment is the characterization of the potential adverse health effects of human exposure to environmental hazards.

2.1.2.1 Hazard Identification

Hazard identification involves the use of exposure and effects data from the laboratory and the field to determine whether the agent of concern can cause a particular adverse health effect (NRC, 1983). The breadth and complexity of most ecological systems may require considerable effort initially to define the scope of the problem, including identifying the stresses involved (whether chemical or nonchemical), the type of ecosystem(s) involved (aquatic, terrestrial, wetlands, etc.), spatial and temporal scaling factors (Harwell, Appendix A), and the endpoints that will be the focus of the assessment.

The identification of what is at risk, also referred to as *endpoint* (or *receptor*) *selection*, is critical to the ecological risk assessment process. Ecological endpoints can be chosen at any of several organizational levels, from biochemical and cellular levels through individuals, populations, communities, and ecosystems. Endpoint selection is dependent upon both the ecosystem(s) and stress(es) of concern. Thus, it is important to define these endpoints at the outset of an ecological risk assessment. Suter (1990) referred to the primary endpoints to be protected as *assessment endpoints*. Sometimes assessment endpoints can be directly measured; in other cases, changes in assessment endpoints can only be inferred from changes in other parameters, known as *measurement endpoints*. Measurement endpoints serve as indicators of changes in assessment endpoints and can be directly determined. For example, an assessment endpoint might be reduced production of green sunfish in a stream receiving a toxic leachate. If sunfish production could not be directly determined due to time limitations or confounding variables in the field environment, the measurement endpoint might be a fathead minnow LC_{50} for the leachate. When the measurement and assessment endpoints are not the same, a clear relationship must be shown between the two types of endpoints (Suter, 1989).

Colloquium participants discussed the basis for selecting a particular set of ecological endpoints in an assessment. If ecological risk assessment guidelines were to recommend a hierarchy of endpoints, Harwell (Appendix A) suggested emphasizing ecological endpoints of particular concern to humans. Others thought that the introduction of "human concern" as a criteria for selecting endpoints moves the focus from risk assessment to risk management. One participant suggested that risk assessors provide risk managers with decision criteria for selecting from the ecological endpoints used in a study, but there was considerable disagreement on this point. It was generally agreed that the risk assessor should start with an extensive list of possible endpoints and select those that are most relevant for a particular type of study. Participants also agreed that ecological risk assessment guidelines should discuss the utility of different types of tests available for endpoint measurements rather than specify particular test procedures.

2.1.2.2 Dose-Response Assessment

Dose-response assessment characterizes the relationship between administered dose and the incidence of an adverse effect. In human health risk assessment, when administered doses are plotted against the measured responses, extrapolation methods typically are used to estimate the response at low doses. Assumptions are also made about the comparability of the animal response to that expected in humans exposed to the same chemical (NRC, 1983).

Stress-response may be a better term than dose-response when discussing ecological risk assessment, since ecosystems can be adversely affected by many different types of anthropogenic stresses, not only toxic chemicals. In fact, comparative risk projects have identified some of the most important ecological stresses as nonchemical, including global climate change, ozone depletion, and habitat alteration (U.S. EPA, 1990a,b). Participants generally agreed that habitat alteration should be addressed in future ecological risk assessment guidelines, and some suggested that EPA could benefit from coordination with the U.S. Fish and Wildlife Service (FWS). FWS regularly conducts habitat evaluations and has developed a formal Habitat Evaluation Procedure.

A stress-response assessment can be conducted once the appropriate assessment and measurement endpoints have been selected. Data used can vary widely depending upon the test protocol--whether the experimental design includes structure-activity relationship analysis, laboratory tests with single species, laboratory microcosms, or full-scale field tests. Extrapolation issues are significant, including the considerations involved in extrapolating among endpoints, species, and levels of biological organization and from laboratory to field situations. Analysis of the uncertainties associated with these extrapolations is discussed in Section 2.1.2.4, Risk Characterization.

2.1.2.3 Exposure Assessment

In human health assessment, the risk assessor conducts an *exposure assessment* to measure or estimate the magnitude, frequency, and duration of exposure, and to characterize the human populations that are subject to exposure (NRC, 1983). In an ecological context, exposure more frequently refers to the concentration or magnitude of a contaminant or stress in the environment. Characterization of the exposed population is particularly problematic in ecological risk assessments. While demographics and activity patterns are frequently available for human populations, ecological risk assessment generally deals with a diverse group of species, about which relatively little is known. There is also a tremendous diversity of habitats, ranging from aquatic environments (sediment, freshwater, and marine) to wetland and terrestrial environments. In ecological exposure assessments, it is important to consider feedbacks within the biota as well as chemical partitioning, remobilization, and export from the ecosystem (Harwell, Appendix A).

Harwell pointed out at the first colloquium (Appendix A) that ecological exposure assessments are generally based on the frequency and duration of inputs of a chemical, its fate and transport in the environment, and any chemical transformations. Suter (Appendix A) suggested integrating the probabilistic properties of pollutant release into transport and fate models that would give estimates of the concentrations and persistence of the pollutant in different environmental media (soil, water, etc.). These probabilistic properties could include pollutant characteristics, such as degradation rate, and environmental characteristics, such as river flow rate. When combined with information on characteristics of the organisms of concern (e.g., rate of consumption of contaminated food), these data could be used in an exposure model to provide probabilistic estimates of accumulated dose through time.

In ecological risk assessment, anthropogenic stresses other than chemical inputs may need to be considered. Examples of nonchemical stresses include:

- Global climate change, which produces changes in air temperature, precipitation amounts and distribution, and storms, and a rise in sea level
- Stratospheric ozone depletion, which increases UV-B radiation
- Ionizing radiation
- Sedimentation
- Species introduction and losses
- Habitat alterations, such as wetlands drainage, conversion of forests and grasslands for agriculture, coastal dredging, clear-cutting of forests, and urban development

Indeed, the recent Relative Risk Reduction Strategies Reports (U.S. EPA, 1990a, b) clearly identified nonchemical stresses from human activities as posing the highest risks to the environment. Consequently, it is important that nonchemical stresses are accommodated in the development of ecological risk assessment methodologies.

The ability of an ecosystem to recover from stress is another important factor to be considered. The ultimate effects of stress on an ecosystem depend not only upon the strength and duration of the initial stress, but also the ecosystem's ability to regenerate. Regeneration is influenced in turn by the scale of the stress-induced physical and biological alterations, the potential for habitat re-establishment, and sources of populations (refugia) for recolonization (Harwell, Appendix A).

2.1.2.4 Risk Characterization

In characterizing risk, the assessor estimates the incidence of an adverse human health effect under conditions defined in the exposure assessment, and describes the uncertainties in the data (NRC, 1983). In an ecological risk assessment, the probabilities of adverse effects at estimated exposure levels are not usually determined. Colloquium participants generally agreed that the process of *ecological risk characterization* does not always have to be quantitative; Harwell (Appendix A) pointed out that relative predictions or rankings of ecological risk can be quite useful to risk managers. This point is well illustrated in the SAB Relative Risk Reduction Strategies Committee's recommendations (U.S. EPA, 1990a).

The description of uncertainties is another important aspect of ecological risk assessment. Uncertainty can originate from many sources, including variability encountered during data gathering, and assumptions used in making extrapolations between endpoints or ecosystem types (Harwell, Appendix A). Harwell stated that much uncertainty can result from errors in the extrapolations associated with different types of tests, such as single-species laboratory tests, artificial microcosms, cores or enclosures, models, and intact ecosystem manipulations.

2.1.3 Paradigms for Ecological Risk Assessment

Suter (Appendix A) described two types of approaches that could be applied to ecological risk assessment: *predictive* and *retrospective*. Predictive assessments deal with proposed actions, such as the introduction of new chemicals, new sources of environmental releases, or possible accidents. In general, the predictive approach follows the four-step NAS paradigm. Hazard identification includes selecting the endpoint(s), describing the environment under consideration, and determining pollutant sources. Dose-response assessment is replaced by effects assessment, which may involve the use of models to project the effects of stresses on selected endpoints. Exposure assessment and risk characterization follow.

In addition to predicting the potential effects of proposed actions, ecological risk assessors frequently are faced with determining whether adverse ecological effects have occurred as a result of previous actions, through a retrospective risk assessment. A retrospective risk assessment would be used, for example, at an abandoned hazardous waste site to determine whether ecological impacts have occurred. In contrast to predictive risk assessments, in retrospective assessments both the source(s) of pollution and the polluted environment may be observed directly. The purpose of a retrospective study is to define the relationship between pollution source, ecosystem exposure, and ecosystem effects.

Suter identified three starting points for retrospective ecological risk assessments (Appendix A)

- Epidemiological Data. Epidemiological assessments use direct field measurements to identify adverse effects and determine their significance, and to establish whether there is a relationship between these effects and potential sources of stress.
- Toxicity Data. If it is impractical to measure effects directly, toxicity-based assessments may be conducted using either ambient toxicity tests or laboratory toxicity tests with environmental media (effluents, soil, etc.).
- Modeling. If an epidemiological or toxicity-based assessment cannot be conducted, a model-based risk assessment can be conducted. This approach resembles a predictive assessment in that it starts with the potential source(s) of the stress and proceeds through the paradigm, modeling pollutant fate and exposure and using data available from conventional laboratory toxicity tests.

2.1.4 Paradigm Selection Summary

While there are many similarities between the paradigm for human health risk assessment and the processes used for ecological risk assessment, there are major differences as well. Based upon the discussions at the first colloquium (Appendix A) and the background information provided (available from EPA; listed in Appendix H), colloquium participants made the following recommendations:

- Terminology used in ecological risk assessment must be defined clearly. For example, the terms hazard assessment and risk assessment are not used consistently in ecological evaluations.

- When applied to ecological risk assessment, it is important that the hazard identification process evaluate chemical and nonchemical stresses, the type of ecosystem(s) involved, and the spatial and temporal scales of possible effects. The hazard identification process should also identify the ecosystem component at risk (that is, specify assessment and measurement endpoints).

- Stress-response may be a better term than dose-response for ecological risk assessment, because of the importance of nonchemical stresses such as habitat alteration. Uncertainties in the stress-response assessments, may come from extrapolations among endpoints, species, and levels of biological organization, and from laboratory tests to field situations. The potential for recovery of structural or functional ecosystem impacts is an important property of ecological systems that should be included in the risk guidance.

- Exposure assessments for ecological risk can involve a diverse group of species, habitats, and stresses. For chemical stresses, fate and transport need to be considered, as well as the frequency and duration of exposures. Chemical bioavailability is an important issue, since ambient chemical concentrations are usually measured rather than delivered dose. For nonchemical stresses, the exposure assessment generally attempts to distinguish between natural and anthropogenic sources and variances of stresses, as well as the appropriate temporal and spatial (e.g., local, regional, or global) scales for the overall assessment.

- In characterizing ecological risks, it is preferable that probabilities of adverse effects at the estimated exposure levels be quantified. Uncertainties due to the use of models, parameter estimation, extrapolations, and other sources of error are generally identified and quantified whenever possible. It is important to recognize, however, that nonquantitative, relative risk assessments or risk rankings may be quite useful.

- Ecological risk assessment may utilize more than one paradigm because of the range of biological, temporal, and spatial scales involved in ecological systems and the potential complex interactions among multiple anthropogenic (chemical and nonchemical) and natural stresses. In addition, ecological risk assessment paradigms need to address both predictive assessments (which determine the possible effects of new chemicals, effluents, etc.) and retrospective assessments (which evaluate whether adverse impacts have occurred as the result of previous actions).

2.2 UNCERTAINTIES IN HAZARD ASSESSMENT

2.2.1 Background

Hazard assessment is defined and used in human health and ecological assessments in many different ways (NRC, 1983; SETAC, 1987; U.S. EPA, 1988a). Hazard assessment is defined operationally in this report as conceptually equivalent to dose-response assessment (NRC, 1983) and effects assessment (Suter, Appendix B). Specific topics encompassed by hazard assessment include species and endpoint sensitivities; acute and chronic dose-response relationships; and taxonomic, endpoint-to-endpoint, and lab-to-field extrapolations and their uncertainties.

The issue of uncertainty was a common and important element in all colloquium discussions. It is not the purpose of this report to present a comprehensive treatment of the uncertainties associated with risk analysis because this topic has been thoroughly discussed elsewhere (Suter et al., 1983; Hattis and Smith, 1986). The essential point is that risk assessments are performed for a number of different purposes, may use different paradigms, and treat uncertainties differently. Since uncertainties are an inherent part of the risk assessment process, it is useful to identify the primary sources of uncertainty, quantify them with the appropriate analytical and statistical procedures, and estimate the magnitude of uncertainties to be expected based on available data.

A principal source of uncertainty associated with hazard assessment is the selection of the assessment model which describes the qualitative and quantitative relationship between the assessment endpoints (the elements at risk) and the measurable endpoints (the attributes of the components at risk). Uncertainties also arise directly from errors in parameter measurement, and indirectly from extrapolations among toxicological endpoints and taxonomic categories, and between laboratory and field. The following discussion illustrates both the sources and magnitudes of uncertainties associated with aquatic and terrestrial hazard assessments. Specific methods used to estimate the uncertainties can be found in the referenced papers. The tables presented in the following sections are based on studies of single chemical contaminants described by the colloquium participants, and are included solely to illustrate the magnitudes of uncertainty associated with different types of extrapolations. The specific values reflect the quantity, quality, and types of data used in the analyses and should not be generalized.

2.2.2 Species Sensitivity

Generally, for single chemicals, the range of toxicity to aquatic organisms varies from 3 to 4 orders of magnitude for acute effects, and 1 to 2 orders of magnitude for chronic toxicity (Slooff et al., 1983; Hansen, 1984). Analyses of relative sensitivities indicate that no aquatic species is consistently the most sensitive across all chemicals (Kenaga, 1982; Mayer et al., 1986; Suter and Rosen, 1988); however, of the taxa considered, penaeid shrimp and mysid shrimp appear to have the highest average sensitivity. Next in sensitivity are crustaceans, which are generally more sensitive than fish (Suter and Rosen, 1988). To account for this range in sensitivity, uncertainty factors are applied to the results of a single-species toxicity test to estimate the safe or acceptable chemical concentration for a specific untested species.

The National Water Quality Criteria Guidelines address this issue by fitting a statistical distribution to toxicity test data for all species tested with the same chemical, then selecting the concentration that will protect a certain percentile of the species tested. The assumption implicit in this approach is that the range of sensitivities is both randomly selected from the community at large and is representative of the species' actual sensitivities in the environment.

2.2.3 Endpoint Sensitivity

Mayer et al. (1986) described the sensitivity of a suite of 20 chronic endpoints to 28 chemicals in 7 species of freshwater fish. The endpoints included survival, growth, reproduction, histopathology, clinical characteristics, disease susceptibility, gill ATP-ase, behavior, and swimming performance. Reproduction was always more sensitive than all other endpoints. The sensitivity of survival equaled or exceeded that of the endpoints (except reproduction) 56 to 69 percent of the time (Mayer et al., 1986; Hansen, 1984). Both univariate and frequency analyses indicated that the no-observed-effect concentration (NOEC) probabilities for survival were within an order of magnitude of all other endpoints 95 percent of the time (Table 2-1).

In a related study mentioned at the second colloquium (Appendix B), Tucker and Leitzke (1979) concluded that no more than a six-fold difference in median effect concentrations can be produced using any known biochemical, histological, or behavioral effect as the endpoint in place of lethality. These and other results suggest that if the desired endpoint of an aquatic risk assessment is chronic effects on fishes, and that if risk is extrapolated from the single measured parameter of fish survival, then an uncertainty of approximately one order of magnitude could be associated with that extrapolation.

2.2.4 Endpoint Extrapolations

Historically, many regulatory decisions are based upon chronic toxicity data. However, because most available toxicity data are acute, the risk assessor needs to understand acute-to-chronic extrapolations and be able to estimate the uncertainties associated with decisions based on these types of extrapolations. Suter et al. (1983), using regression analysis, compared the maximum acceptable toxicant concentrations (MATCs) with acute toxicity LC_{50} values derived from the same study using marine fishes and crustaceans. In this case, the uncertainty associated with estimating chronic toxicity (MATC) for all marine fishes from acute toxicity data for all chemicals was a factor of about 20. Similar analyses resulted in uncertainty factors of approximately 34 for freshwater fishes, 10 for marine crustaceans (90 percent *M. bahia*), and 22 for the freshwater cladoceran (*Daphnia* sp.). These laboratory data suggest that a risk assessor can expect an uncertainty range of 10- to 40-fold when extrapolating from acute to chronic toxicity for single compounds and aquatic organisms. However, the degree to which these laboratory-estimated uncertainties apply in the natural environment has not been resolved.

TABLE 2-1

SOURCES AND RANGES OF UNCERTAINTY IN AQUATIC HAZARD ASSESSMENTS

Sources of Uncertainty	Uncertainty Factors
Species Sensitivity Ranges	
Acute toxicity	1,000-100,000
Chronic toxicity	100-1,000
Endpoint Sensitivity (Fishes)	
Survival-NOEC : Reproduction	11
Survival-NOEC : Chronic endpoints (nonreproductive)	4.6-7.5
Endpoint Extrapolations (Fishes)	
Acute : Chronic (Marine)	18
Acute : Chronic (Freshwater)	34
Endpoint Extrapolations (Invertebrates)	
Acute : Chronic (Marine)	8
Acute : Chronic (Freshwater)	22

Sources: Mayer et al., 1986.
Suter and Rosen, 1988.
Suter et al., 1983.

2.2.5 Taxonomic Extrapolations

Extrapolations among taxa are based upon the assumption that taxonomic similarity results in toxicological similarity, and that a species' responses will be more similar to those of congeneric species. Consequently, as taxonomic similarity decreases, extrapolation uncertainty increases. This is illustrated for marine and freshwater acute toxicity data for single chemicals by the increased uncertainty associated with moving up the taxonomic hierarchy (Table 2-2) (Suter and Rosen, 1988). For example, the extrapolation uncertainties for marine and freshwater fishes increases from approximately a factor of 5 for extrapolations within congeneric species to a factor of 10 for extrapolations among families and a factor of 20 or more for orders. These data suggest the magnitudes of uncertainty to be expected when extrapolating from acute toxicity tests to estimate acute toxicity of the same chemical to untested species in the same or different taxons.

2.2.6 Laboratory-to-Field Extrapolations

A number of studies evaluated the ability of single-chemical laboratory toxicity test results to predict adverse effects of the same chemical on aquatic organisms under field conditions. One such study described at the second colloquium predicted field mortalities of estuarine organisms resulting from pesticide runoff, and compared the measured mortality rates to those predicted from acute toxicity laboratory tests. The toxicity tests estimated LC_{50}s from constant, single-pulse, and multiple-pulse pesticide exposures (Mayer, Appendix B). Preliminary results suggest that:

- The multiple-pulse laboratory exposure corresponded most closely to observed field effects.
- Exposure-response relationships were similar in the laboratory and field.
- Laboratory toxicity tests represent more conservative exposure scenarios than occur in nature.
- Concentrations of chemicals causing no effect to caged individuals of resident estuarine species also do not appear to affect communities of estuarine biota.

TABLE 2-2

SUMMARY OF FRESHWATER AND MARINE TAXONOMIC EXTRAPOLATIONS FOR LC_{50}s

Taxonomic Level	n[a]	Mean of 95% Prediction Intervals[b]	
Species			
Marine fish	1	0.75[c]	(5.6)[d]
Freshwater fish	8	0.76	(5.8)
Freshwater arthropods	2	1.10	(12.6)
Genera			
Marine fish	1	0.82	(6.6)
Freshwater fish	8	0.74	(5.5)
Freshwater arthropods	2	0.78	(6.0)
Families			
Marine fish	3	1.00	(10)
Freshwater fish	4	0.97	(9.3)
Marine crustaceans	7	0.94	(8.7)
Freshwater arthropods	3	1.37	(23.4)
Orders			
Marine fish	13	1.27	(18.6)
Freshwater fish	10	1.35	(22.4)
Marine crustaceans	4	2.38	(24.0)
Freshwater arthropods	10	2.06	(115)

[a] n = the number of pairs of taxa at that taxonomic level.
[b] weighted by the number of points (chemicals) in each regression.
[c] Log units.
[d] Anti-log.

Source: Suter and Rosen, 1988.

- Communities of benthic organisms appear unaffected by contaminated sediment that is determined nontoxic in laboratory tests.

Complex effluent testing has been the subject of EPA's Complex Effluent Toxicity Testing Program. Preston (Appendix B) reviewed the correlation of ambient (in-stream) freshwater toxicity measurements to receiving water community impacts. Results indicate a high positive correlation between the results of complex effluent toxicity tests in fresh water and observed impacts on receiving waters. Positive effects for both toxicity and community response (e.g., reduction of taxa) were set at 20 percent. Of 83 freshwater stations studied, false positives occurred at only 3.6 percent and noncontradictory findings were reported for 96.4 percent (Preston, Appendix B).

2.2.7 Biomarkers in Ecological Risk Assessment

NAS defines biological markers (biomarkers) as indicators of variation in cellular or biochemical components of processes, structure, or function that are measurable in biological systems or samples (U.S. EPA, 1988e). The availability, development, and interest in biomarkers is in part due to the expanding understanding of biological processes, particularly those at the molecular level. The use of biomarkers as indicators of effects and exposure in monitoring and assessment programs was discussed briefly at the second colloquium.

Biomarkers can be divided into two categories: measures reflecting exposure or susceptibility to a stress, and measures of biological effects. In fact, the distinction between these two applications often is blurred, particularly when the biomarker serves both functions (e.g., carboxyhemoglobin) (U.S. EPA, 1988e). The appeal of biomarkers for applications in human health and ecological assessments is their ability to provide early detection of adverse biological effects due to stress.

Some researchers, however, identified problems associated with the application and interpretation of biomarkers in the ecological assessments used in monitoring programs (Mehrle and Mayer, 1980; Widdows, 1982; Gentile et al., 1990). The confusion stems from the tendency to treat biomarkers as assessment endpoints, rather than measurement or detection endpoints. Specifically, subcellular biomarker responses are often extrapolated across biological scales to infer system-level impacts. Because the number of compensatory and adaptive mechanisms increases with system complexity, considerable uncertainty exists in predicting ecological impacts from measures of cellular response (Capuzzo, 1981). One participant cautioned against using biomarkers as predictors of more traditional toxicity testing endpoints and suggested that biomarkers not be used alone, but in batteries of assays. Biomarkers can complement, not replace, standard testing, he added.

2.2.8 Avian Hazard Uncertainties

The information related to terrestrial ecosystems that was presented at the colloquium on hazard uncertainties focused primarily on avian toxicology. The existing data bases, although limited, did indicate that interspecies differences in avian mortality to the same chemical ranged from 30 to 60 while interspecies differences in avian reproduction varied by a factor of 300. Colloquium attendees noted that although there are many years of research on avian toxicology, the data base is still small compared to the aquatic data bases. The colloquium participants agreed that lethality and reproductive effects are the two primary endpoints used in avian toxicology and that one would expect correspondence between laboratory and field studies for these endpoints. The participants suggested that because the terrestrial data bases were not as extensive nor as well analyzed as the aquatic data bases, terrestrial risk assessment guidelines could not be as comprehensive as aquatic guidelines at this time.

2.2.9 Additional Extrapolation Uncertainties

The following extrapolation issues, discussed at the colloquia and meetings, are relevant to the development of future ecological risk assessment guidelines.

2.2.9.1 Dose Scaling and Allometry

Applications of dose scaling were discussed for both aquatic and terrestrial systems, as well as for human health. It has been proposed that scaling factors may help to account for differences in pharmacokinetics, pharmacodynamics, and sensitivity among species. Weight has been used as a scaling factor in aquatic and terrestrial toxicology as well as in human cancer assessments. In cancer risk assessment, the most appropriate scaling factor for mouse-to-human extrapolations is currently a subject of intense discussion. There is evidence that when a mouse and a human are compared physiologically and metabolically, they vary directly as a function of weight to a specified power. Allometric regression can be used to define the relationship between a test endpoint (e.g., mortality) and physical dimension (such as size), thus permitting the prediction of the response in an untested species from its dimension. Physiological time is also being studied as a scaler for rate functions because many species-specific differences can be accounted for by differences in the rates of metabolism and excretion.

2.2.9.2 Temporal Variation

Historically, time (and consequently exposure) is a fixed variable in most standard toxicity tests, yet in reality environmental exposures are more likely to be both concentration- and time-variable. Data relating exposure duration and magnitude to a specific response are collected from standard toxicity tests but may not be reported. Participants recommended making better use of available test data on organism response at different durations of exposure. Mayer (Appendix B) suggested using a plot of the LC_0 calculated from acute toxicity test data against the reciprocal of exposure time to estimate chronic lethality. Using the whole data set significantly reduces uncertainties that result from extrapolating among these variables (Suter, Appendix B).

2.2.9.3 Chronic Endpoints

Statistical measures of chronic response, such as MATCs, lowest- and no-observed-effect concentrations (LOECs, NOECs), are often used as "thresholds" for chronic toxicity. The assumption that these statistically derived thresholds represent toxicant concentrations causing "acceptable" levels of biological effect has been questioned. Stephan and Rodgers (1985) have shown that these "acceptable thresholds" are often set at concentrations causing greater than 50 percent mortality.

A recent analysis of endpoints for fishes' responses to chronic toxic exposure (Suter et al., 1987) demonstrated that the most sensitive chronic effect was fecundity. The reported MATCs corresponded to the following levels of effect: parental survival, 20 percent; fecundity, 42 percent; hatching, 12 percent; larval survival, 19 percent; weight, 20 percent; and weight/egg, 35 percent. These observations are particularly important since population models using these parameters as inputs could show significant decreases in abundance, and an increased probability of quasi-extinction. Though not explicitly stated by colloquium participants, this information:

- Points out difficulties in using MATCs as "acceptable" toxicity thresholds or for extrapolating to untested taxa.
- Suggests that the uncertainties associated with the use of these values be included with "quotient"-type hazard assessments.
- Fosters the development of chronic toxicity methods based upon regression analyses and their uncertainties, rather than analysis of variance.

2.2.10 Summary of Hazard Uncertainties

For the most part, colloquium discussions focused on the uncertainties in extrapolations using laboratory data that emphasizes individual- and population-level responses to single chemical stresses. This approach has a strong historical basis and consequently is supported by extensive data bases. Models have been developed for extrapolating among endpoints, taxa, and media with known degrees of uncertainty. However, the ability of this type of laboratory data to predict "real world" effects may be limited by: (1) variations in physical and chemical environmental factors; (2) multiple chemical interactions; (3) chemical-physical interactions; (4) nonchemical stresses; (5) biotic interactions; and (6) indirect biological effects that are not explicitly determined in laboratory tests. The importance of these limitations to an ecological risk assessment depends upon application of the assessment. Harwell (personal communication in reviewing this report) has suggested that community- and ecosystem-level exposure and effects endpoints may have less uncertainty than individual- and population-level endpoints in some situations. For example, predictions of the effects of temperature change on the distribution of ecosystem types and biomes are more reliable than similar predictions for individual species within those systems. Also, predictions of the reestablishment rate of species diversity following the slash-and-burn destruction of a tropical rain forest may be more reliable than predictions of where and when a particular species will recover. The selection of appropriate community- and ecosystem-level endpoints can reduce the uncertainty in predictions by integrating individual component variation and functional redundancy at the broader temporal and spatial scales needed for certain types of ecological risk assessments.

Within the context of the above assumptions and limitations, the information presented at the colloquia and in the literature presented by colloquia participants illustrates the sources and magnitudes of uncertainties associated with ecotoxicity assessments for single chemicals, including:

- Species sensitivity comparisons indicate that no aquatic species is consistently the most sensitive across all chemicals. However, crustaceans are more sensitive, on average, than fishes.
- Endpoint extrapolations from acute to chronic toxicity range from about 20- to 35-fold for fishes and from 10- to 20-fold for crustaceans. Chronic survival in fishes, however, can be used to predict all other chronic fish responses within a factor of 10 (one order of magnitude) 95 percent of the time.
- Taxonomic extrapolation uncertainties increase with decreasing taxonomic similarity (from species to family) by factors of 5 to 20 for fishes, 10 to 25 for crustaceans, and from 10 to 100 for freshwater arthropods.

- Laboratory-to-field extrapolations incorporate both exposure and hazard uncertainties. Exposure uncertainties often can be greater than uncertainties associated with endpoint and taxonomic extrapolations.

- Terrestrial toxicity data bases and extrapolation models are not as well developed as those for aquatic toxicity. Data presented for avian toxicity showed interspecies extrapolation uncertainty factors of 30 to 60 for mortality and up to 300 for reproduction.

- Biomarkers can be used alone as useful indicators of exposure to toxicants, but to be useful indicators of higher level effects (i.e., population, community, ecosystem) it is important to understand their relationship to important whole-animal responses.

- Extrapolation uncertainties can be reduced by scaling dose or exposure to weight or physiological time, through the use of allometric regressions, and by using exposure-response regression models rather than single-point statistical estimates of threshold concentrations (e.g., MATC, NOEL, etc.).

2.3 UNCERTAINTIES IN EXPOSURE ASSESSMENT

2.3.1 Introduction

Exposure assessments are fundamental to the conduct of risk assessments, as they identify the populations, communities, and ecosystems at risk, and also can determine compliance with existing standards. Exposure assessment involves measuring or predicting the magnitude, frequency, duration, and probable routes of exposure of the segment of the population or ecosystem at risk to stress(es) present or anticipated in the environment (NRC, 1983). Most importantly, this process identifies and quantifies (when possible) the individual and propagated uncertainties in the process.

For individual organisms, exposure may be defined as the contact of a chemical, physical, or biological agent with the outer boundary of the organism. The use of the term "dose" for assessing the impact of exposure to environmental contaminants on populations and ecosystems is problematic because it seldom can be measured directly (U.S. EPA, 1988b). Thus, exposure concentrations rather than doses are usually reported in ecological assessments.

The goal of exposure assessment is to quantitatively couple estimates or measures of exposure concentration and frequency and duration of contact with the population or ecosystem compartment at risk. The following data are useful for estimating exposure to chemical stresses:

- Source characterization. Estimations of the magnitude and patterns of release of the chemical in the environment.
- Transport. Estimates or measurements of the chemical's spatial and temporal patterns of movement through one or more media.
- Transformation. The biotic and abiotic transformations of the chemical.
- Exposure concentrations. The magnitude, frequency, and duration of environmental concentrations or metabolites within prescribed spatial scales.
- Routes of exposure. The principle routes of exposure, i.e., ingestion, dermal/surface contact, and inhalation/respiration.
- Activity patterns and species abundance. The organism's behavior and population distribution patterns that result in contact with the chemical.

Exposure assessment for nonchemical stresses involves many of the same concepts as for chemical stress: identification of the important targets within an ecosystem potentially affected by a stress (including population-, community-, and ecosystem-level endpoints); characterization of the exposure regime with respect to frequency, intensity, and duration of stress; and modification of the stress as it interacts with the environment (e.g., absorption of UV-B as it passes through a forest canopy or through the euphotic zone in aquatic ecosystems). However, there are differences between exposure assessments for chemical and nonchemical stresses. For chemicals, much of exposure assessment revolves around fate and transport modeling, with attention to partitioning and bioavailability of the chemical and its derivatives based on the chemical's characteristics (e.g. octanol-water partitioning [K_{ow}] as an indicator of lipid versus water solubility). This aspect of chemical exposure assessment is not applicable for most nonchemical stresses. In contrast, nonchemical stresses are often changes in the amount or distribution of a part of the natural environment, such as temperature or precipitation. Consequently, an important aspect of exposure assessment for nonchemical stress is distinguishing an anthropogenic stress from natural levels and variances of the same physical parameter.

2.3.2 Environmental Exposure Assessments

Although Agency guidance (U.S. EPA, 1986e) has been developed for conducting exposure assessments, the existing guidelines focus primarily on human exposure assessment, and therefore do not address many of the issues peculiar to ecological exposure assessments. Colloquium participants were asked to identify important considerations in ecological exposure assessment, to discuss the status of current knowledge in these areas, and to identify potential sources of uncertainty (Appendix C). The participants identified issues relevant to the design, conduct, analysis, and interpretation of exposure assessments for use in ecological assessments. These issues include:

- The importance of clearly defining exposure in terms that are compatible with the spatial, temporal, and biological scales of the risk assessment.
- Identifying the routes of exposure and determining the importance of behavior and activity patterns as modifiers of exposures.
- Determining useful indicators and measures of exposure at various scales.
- Identifying and estimating the sources and magnitudes of uncertainties.
- Extrapolating between laboratory and field observations.
- Understanding the factors that determine the rate and extent of recovery in ecological systems from single and multiple exposures.

2.3.3 Exposure Concepts

The colloquium participants discussed the following approaches to describing environmental exposures that differ in complexity, data requirements, and measurement uncertainty, beginning with the simplest way to define chemical exposure:

- Exposure can be expressed as the total concentration of a chemical in water, sediment, and biota without regard to bioavailability or contact with specific populations or ecosystem components at risk. This results in a value that can have a low degree of measurement uncertainty but may have little ecological relevance.

- A more complex expression of exposure includes the routes and rates of exposure and functional statements that describe the magnitude, duration, and frequency of exposure. This definition recognizes the importance of behavior and activity patterns as modifiers of exposure. It also has a higher degree of measurement uncertainty, but begins to reflect actual exposures more realistically.

- One can further increase the realism of environmental exposure estimates by introducing the chemical's bioavailability to the population or ecosystem component at risk. This definition includes the concepts of partitioning, degradation, and metabolism. The feasibility of incorporating bioavailability into an expression of exposure depends upon the physical and chemical properties of the chemical, availability of conceptual and analytical models, the data, and the biological system at risk. This expression of exposure has several additional sources of uncertainty but can have a high degree of biological relevance.

- The most detailed and complex definition of exposure can be referred to as the biologically effective exposure. This describes the magnitude, extent, and temporal patterns of exposure resulting from the summation of routes, rates, transformations, and bioavailability, using appropriately calibrated models. This level of complexity can have an extremely high degree of measurement uncertainty and involve complex pharmacodynamic models. The ecological relevance of this measure of exposure is a function of the scale of the assessment.

2.3.4 Routes and Patterns of Exposure

The three principal routes of exposure for terrestrial, avian, and aquatic species are:

- Ingestion
- Dermal/surface contact
- Inhalation/respiration (e.g., gills for aquatic species)

Colloquium participants discussed the relative contribution of these individual exposure routes to the overall exposure for the organism or system. In both aquatic and avian species, the importance of individual routes varies with the species, habitat, organism behavior, body size/biomass ratios, the chemical properties of the contaminant, feeding type (e.g., filter, deposit feeders, etc.), habitat use patterns, and contaminant bioavailability. The relative importance of these variables is particularly difficult to quantify for avian species. The large number of species and their varying physiological characteristics, their eating and grooming habits, and their annual and daily migratory practices were identified as confounding factors by colloquium participants. Consequently, generalizations have been limited to single media, a single stress, and taxa with similar trophic positions, life histories, and feeding strategies.

2.3.5 Exposure Indicators

Indicators of exposure can be developed for each major component in the exposure assessment. Exposure indicators are not necessarily measures of adverse biological effects in themselves but can provide information about the exposure of various ecosystem components. Colloquium participants identified the following categories of indicators:

- Chemical indicators (e.g., tissue residues)
- Biochemical and cellular indicators of metabolic transformations (e.g., DNA/RNA, P-450, protein adducts)
- Organism-level indicators of exposure (e.g., growth, disease, fecundity, etc.)
- Behavioral indicators (e.g., breeding, feeding, etc.)
- Indicators of habitat degradation and modification
- Indicators of system function (e.g., carbon fixation and cycling, nutrient flux and recycling, etc.)

The assumptions and limitations that govern the application and interpretation of exposure indicators need to be considered by the risk assessor. For example, exposure indicators provide only a point estimate of the exposure regime, and successive measurements over a long time are necessary before statements can be made about trends in exposure. Also, it is difficult to discriminate between anthropogenically induced stress and natural changes in the indicator. Finally, criteria should be developed for determining the statistical and ecological significance of changes in the indicator before the indicator is used in a risk assessment.

One colloquium speaker suggested the use of the sentinel species concept for determining the spatial and temporal scales of environmental exposures. This concept was the basis of EPA's "Mussel Watch" and the National Oceanic and Atmospheric Administration's (NOAA's) "Status and Trends" monitoring programs. In the sentinel species approach, an indicator species is selected for monitoring or detecting the presence and patterns of change of a chemical or nonchemical stress in the environment. Criteria for selecting sentinel species include knowledge of the organism's sensitivity to stresses, position in the community, likelihood of exposure, and geographical and ecological distribution or abundance.

2.3.6 Exposure Uncertainties

When conducting an environmental exposure assessment, the assessor should consider the uncertainties associated with each step. Some sources of uncertainties include:

- Variations in the composition, magnitude, frequency, and duration of the release or discharge.
- Knowledge of the chemical's physical and chemical properties (e.g., solubility, persistence, log K_{ow}).
- The temporal and spatial scales of exposure, and matching those scales with the biological scales of the risk assessment.
- The temporal and spatial heterogeneity of the stress, as well as the heterogeneity of the populations (abundance, life stages, etc.) at risk.
- Knowledge of the alterations in the stress (e.g., chemical transformation) due to chemical, physical, and biological action.

- Interactions among multiple stresses that alter bioavailability.

The task of the risk assessor is to identify which categories and sources of uncertainty predominate in a specific problem setting and ensure that the uncertainties are adequately addressed.

2.3.7 Multiple Exposure and Recovery of Ecological Systems

Inferring ecological risks draws upon knowledge of a population, community, or ecosystem's resilience, or ability to recover from a perturbation. Ecological resiliency depends upon several important factors. Yount (Appendix C) described several organizing principles to evaluate the rates, patterns, and dominant factors governing the recovery of lotic communities:

- Recovery Theory. Theoretical models such as secondary succession, island biogeography, and natural selection can be used to study recovery.
- Endpoint Selection. One can characterize recovery, the chosen endpoint, as a return to pre-disturbance conditions, the establishment of a new stable equilibrium, expansion to normal boundaries for existence, or by comparison to a surrounding unstressed area.
- Disturbance Categories. Pulse disturbances often last less than one generation while press disturbances persist and deform a system over long periods of time. Each produces a different kind of stress on the system.
- System Characteristics. Productive capacity, turnover and generation time, flushing rates, and presence of refugia are critical to the system's rate of recovery from a perturbation.

Based on a survey of more than 150 case studies, Yount and Niemi (1990) reached the following conclusions regarding a system's potential for recovery:

- Refugia (unaffected pockets of the population) are critical to system recovery.
- Recovery rate is dependent upon the magnitude, spatial extent, frequency, and duration of the perturbation.

- Recovery is more rapid from chemical stress than from physical habitat alteration.
- Functional components of an ecosystem recover faster than structural components.

The potential for recovery in ecological systems from single or multiple exposures is often an important factor in developing exposure control strategies. For example, the Water Quality Criteria Program uses a time-dependent recovery component to control for both acute (short-term) and chronic (long-term) exposure-induced impacts. A criteria maximum concentration (CMC) is averaged over 1 hour but can be exceeded at any one point during that interval. Similarly, the criteria continuous concentration (CCC) is averaged over 4 days. Finally, several regulatory statutes employ an exposure control strategy called a "7Q10" that regulates discharges into low flow streams. The 7Q10 approach calculates exposures for the most rigorous exposure conditions, that is, the 7-day low flow expected to occur once in 10 years.

2.3.8 Summary

Ecological exposure assessments take many factors into consideration that are not typically considered in human health assessments. This difficulty is confounded by the fact that often the requisite data base is not available to address several issues, such as behavior patterns and how stress alters these patterns, information on population abundance and distribution, and methods for predicting resiliency and recovery. Ecological exposure assessments are further complicated by the need to consider nonchemical stresses. In contrast to human exposure assessment, ecological exposure assessment is at an early stage of development and risk assessors will have to contend with greater uncertainty for the foreseeable future.

2.4 POPULATION MODELING IN ECOLOGICAL RISK ASSESSMENTS

2.4.1 Introduction

During the past two decades, toxicological endpoints (e.g., acute and chronic toxicity) for individual organisms have been the benchmarks for regulations and assessments of adverse ecological effects. As a result, an extensive toxicological data base has been developed, particularly for fishes and aquatic invertebrates. The question most often asked regarding these data and their use in ecological risk assessments is, "What is the significance of these ecotoxicity data to the integrity of the population?" More importantly, can we project or predict what happens to a pollutant-stressed population when biotic and abiotic factors are operating simultaneously in the environment?

Protecting populations is an explicitly stated goal of several Congressional and Agency mandates and regulations. Thus it is important that ecological risk assessment guidelines focus upon protection and management at the population, community, and ecosystem levels of organization. Participants in the final colloquium discussed the use of population concepts in perturbation analyses, examined several population models of varying degrees of complexity that use laboratory and field data to make population projections, and discussed the application and limitations of these models in a regulatory setting.

2.4.2 Matrix Projection Models

Population modeling is based upon the demographic fact that individuals in populations do only four things: they are born, they age or grow, they have offspring, and they die. In this way, demographic theory provides the framework for modeling the growth and decline of age-structured populations (Ferson et al., 1989). The apparent simplicity in this fact belies the mathematical complexity engendered when these four stages are modeled realistically. Matrix population models incorporate and integrate measures of four organism vital rates (i.e., birth, growth, survival, and reproduction) for each age or stage class and project the resulting demographic properties of the population. These models allow risk assessors to determine the response of three demographic properties of populations (long-term population growth rate, stable age- or stage-class distribution, and age- or stage-specific reproductive value) to environmental or biological factors that cause changes in the individual-level survival, growth, and reproductive rates (Caswell, 1989). Matrix models are useful tools for testing hypotheses and investigating the direct effects of biotic and abiotic factors on the demographic properties of a population because they integrate age- or stage-specific differences in sensitivity to a stress.

Using matrix projection models and life-cycle graphs, Caswell (1989) has developed methods for conducting sensitivity (perturbation) analyses to determine the significance of stress-induced changes in the life cycle coefficients (e.g., survival) on population growth rate (Weinberg, Appendix D). In other words, with sensitivity analysis, the risk assessor can determine the degree to which changes in survival, growth, and reproduction resulting from exposure to a stress will contribute to changes in population growth rates.

Two examples illustrate how sensitivity analysis can be used to determine the significance of changes in organism vital rates to the overall population growth rate. Weinberg et al. (1986) demonstrated a statistically significant increase in adult growth and survival and juvenile growth in the bivalve *Gemma gemma* when it was grown in the presence of a polychaete worm. However, when sensitivity analysis was used to evaluate the contributions of changes in each of these vital rates to changes in the population growth rate, only juvenile growth was found to have an impact on the bivalve population growth rate (Weinberg et al., 1986, Appendix D).

Caswell (1989) used both analysis of variance (ANOVA) and sensitivity analysis to compare the relative contributions of different modes of larval development (lecithotrophic and planktotrophic) to the population growth rate of the polychaete *Streblospio benedicti* (Levin et al., 1987). The results suggest that one cannot assume that large stress-induced changes in organism vital rates (e.g., growth, survival, and reproduction) will translate into large changes in long-term population growth rates (Caswell, 1989). These two examples clearly show that sensitivity (perturbation) analysis can help distinguish the relative importance of statistically significant stress-induced effects on organism vital rates by their contribution to population growth.

Important assumptions and limitations to these matrix population models should be recognized. Matrix projection models assume that the organism's vital rates are age- or stage-independent; the vital rates do not vary in time, space, or with density; and emigration balances immigration for the population. Two limitations of this approach are: (1) it is difficult experimentally to measure certain vital rates, and (2) the model in its simplest form is not suited for predicting the fluctuations in populations characteristic of the field because some of the underlying assumptions are violated. Further, these models often do not include functions for estimating density-dependent factors, species interactions, or important trophic interactions.

However, recognizing these assumptions and limitations, matrix projection models coupled with sensitivity (perturbation) analysis can be used to:

- Understand the importance of changes in specific life history vital rates (e.g., growth rate) to the demographic properties (e.g., long-term growth rate) of the population.
- Estimate the direct effects of individual toxic chemicals upon demographic properties of populations.
- Evaluate alternative management strategies and test hypotheses.
- Provide one type of ecological framework for interpreting the potential consequences of acute and chronic toxicity information.
- Provide the necessary technical basis for incorporating demographic properties of populations into the characterization of ecological risk.

2.4.3 Natural Population Time-Series Models

Fisheries stock-recruitment models that rely on empirical time-series data collected from the field were presented and discussed at the colloquia. Fogarty (1989) thoroughly reviewed methods for quantifying and projecting the effects of perturbations (e.g., harvesting) on recruitment of natural populations. Time-series models account for the variability in recruitment by using historical population response information to predict future responses.

Empirical time-series and autoregressive integrated moving-average models provide better prediction of recruitment than normal stock recruitment models because they incorporate so much more data. These models can be combined with other models to provide a more complete picture of the factors influencing responses and to detect perturbations. The uncertainties associated with these models can be quite large, however, which makes discrimination of natural perturbations from contaminant-induced perturbations difficult at this time.

2.4.4 Stochastic, Density-Dependent, and Spatial Models

Important features absent from the matrix population models discussion in Section 2.4.2 are stochasticity (e.g., replication, coefficients of variability, demographic stochasticity, etc.), density dependence, and estimates of uncertainty. Ginzburg et al. (1982) proposed using quasi-extinction probabilities as standard criteria for environmental assessments. Population models (age- and stage-structured) have been developed for estimating single-species population responses to a single stress (Ferson et al., 1989). These models incorporate stochasticity and density dependence, and use Monte Carlo simulation techniques to estimate the probability of population abundances for a variety of perturbation scenarios. The models provide estimates of both demographic vital statistics and the probability of population abundances falling below a predetermined critical level (e.g., quasi-extinction). These models can be executed on microcomputers (RAMAS/Age, for example) (Ferson et al., 1989) and are useful tools for examining the impacts of various stress or management scenarios on population growth patterns.

Generally, most of the population models described above assume spatial aggregation and do not describe how populations actually behave in nature. To address this, spatial models describe the interactions between multiple populations of the same species (Ginzburg, Appendix D). The spatial structure of a population is an important factor in a population's sensitivity to extinction and loss of habitat, and its response to multiple stresses. Spatial models are still in developmental stages, and as such are useful research tools for testing alternative hypotheses and management strategies, but have limited regulatory utility.

2.4.5 Ecotoxicity Population Models

Methods have been developed for integrating matrix-type demographic models with toxicity data on growth, development, survival, and reproduction. These age- and stage-classified life matrix projection models can be used to infer and project (not predict or forecast) the potential direct impacts of single contaminants on several important population properties (e.g., growth rates, abundances, age distributions, quasi-extinction, etc.) (Ginzburg et al., 1982; Gentile et al., 1982; Barnthouse et al., 1987; Caswell, 1989). It is important to note, however, that these models do not predict the temporal or spatial dynamics of the populations.

Recently, Barnthouse et al. (1990) coupled a matrix-type projection model to a suite of toxicity endpoints and taxonomic extrapolation models to predict the effects on recruitment for striped bass and menhaden populations. Seven categories of traditional toxicity data (see Table 2-3) were extrapolated to provide concentration-response functions for all life stages of the species of interest. The resulting concentration-response functions were then used as input for deterministic or stochastic versions of matrix population models (e.g., RAMAS/Age) (Caswell, 1982) that project a population's demographic properties.

The uncertainties associated with predicting recruitment of menhaden and striped bass from each category of toxicity data are summarized in Table 2-3. As would be expected, the least extrapolation uncertainty (a factor of 1.7) results when there are toxicity data for the complete life cycle of the species of interest. This type of toxicity data provides a complete life table of age- (or stage-) classified toxicity data for all organism vital rates (e.g., survival, growth, development, and reproduction). Extrapolating from a life cycle test with a different species to the species of interest introduces a 50-fold increase in uncertainty. Since accumulated uncertainty in projections increases as the number of endpoint and taxonomic extrapolations increases, extrapolating from acute toxicity data to populations results in from 100- to 500-fold uncertainties. Finally, in the absence of direct toxicity data, population projections extrapolated from physical-chemical properties, or QSAR data, result in uncertainties of 500- to 1000-fold.

TABLE 2-3

UNCERTAINTIES OF PROJECTING FISH POPULATION RISKS FROM TOXICITY TEST DATA

	Uncertainty Factors	
Toxicity Data Type	**Gulf Menhaden**	**Chesapeake Striped Bass**
Life cycle test (species of interest)	0.23[a] (1.7)[b]	0.46 (3.0)
Life cycle test (nonspecies of interest)	1.92 (83)	2.08 (120)
Partial chronic test (species of interest)	1.70 (50)	1.72 (53)
Partial chronic test (nonspecies of interest)	2.14 (138)	2.18 (151)
Acute toxicity (species of interest)	2.17 (148)	2.24 (174)
Acute toxicity (nonspecies of interest)	2.62 (417)	2.45 (282)
Physical-chemistry data (QSAR)	2.82 (661)	2.48 (302)

[a] Log units.
[b] Anti-log.

Source: Barnthouse et al., 1990.

The ecotoxicity-based extrapolations to single aquatic populations of regulatory interest are examples of the use of population theory, properties, and models for estimating the potential risk of direct chemical effects to specific demographic properties (e.g. recruitment) of a population. These models do not predict the consequences of biotic and abiotic modulation upon the demographic properties of the population. Using deterministic and stochastic matrix projection models (Ginzburg et al., 1982; Ferson et al., 1989) along with perturbation and sensitivity analyses (Caswell, 1982, 1989; Weinberg et al., 1986) provides the tools for:

- Projecting the risks to specified valued populations and quantifying associated uncertainties.
- Comparing long-term changes in important population properties resulting from the direct toxicity of single chemical stresses.
- Providing a framework for interpreting toxicity test data, evaluating alternative protocols, and developing decision criteria for tiered testing programs.

2.4.6 Summary

The colloquium presentations, available literature, and discussions on population modeling in ecological risk assessment provided the following information:

- There is a sound scientific basis for applying the principles of population ecology to regulatory issues.
- The available models can estimate demographic properties of populations (e.g., growth rates, abundance, recruitment, elasticity, etc.) from information about natural or stress-induced changes to organism growth, survival, and reproductive rates.
- Deterministic and stochastic population models have been developed for estimating the population's vital statistics (e.g., abundance, quasi-extinction, etc.), and the sensitivity of the population's growth rate to perturbations of its life history stages.
- Ecotoxicity-matrix population models that link the usual categories of direct toxicity data to projections of population characteristics have been developed for

fishes and may be used to support some regulatory decisions encountered within the Agency.

- For fish populations, the uncertainties associated with extrapolating the effects of direct chemical toxicity to a specific demographic property (e.g., impaired recruitment) range from 1 to 2 orders of magnitude when acute and chronic toxicity data on the species of interest are used, to 2 to 3 orders of magnitude for extrapolations from acute toxicity data on a different species or from structure-activity data.

- Using population responses to project impacts to species-specific populations in the field on a routine basis was not considered feasible at this time because field populations are highly variable in space and time and are controlled by density-independent factors that are only modeled stochastically. Further, these models often do not account for important interactions among species (e.g., competition) or trophic levels. Finally, the exact form of the stress-response relationships that may control fish population dynamics are not well known and thus are not explicit functions of the models.

- The use of population responses for terrestrial applications is not as well developed as aquatic applications. The colloquium participants suggested developing generalized life history models to extrapolate among populations in different habitats. For example, aquatic crustaceans' life history strategies are similar to terrestrial insects'.

- The demographic properties of populations can be used to provide an ecological framework for interpreting toxicity data as well as a tool for testing hypotheses and examining alternative management strategies.

2.5 REFERENCES

Barnthouse, L.W., G.W. Suter II, and A.E. Rosen. 1990. Risks of toxic contaminants to exploited fish populations: influence of life history, data uncertainty, and exploitation intensity. Environ. Toxicol. Chem. 9:297-311.

Barnthouse, L.W., G.W. Suter II, A.E. Rosen, and J.J. Beauchamp. 1987. Estimating responses of fish populations to toxic contaminants. Environ. Toxicol. Chem. 6:811-824.

Capuzzo, J.M. 1981. Predicting pollution effects in the marine environment. Oceanus 24:25-33.

Caswell, H. 1982. Optimal life histories and the maximization of reproductive value: a general theorem for complex life cycles. Ecology 63(5):1218-1222.

Caswell, H. 1989. Analysis of life table response experiments. I. Decomposition of effects on population growth rate. Ecol. Modeling 46:221-237.

Ferson, S., L. Ginzburg, and A. Silvers. 1989. Extreme event risk analysis for age-structured populations. Ecol. Modeling 47:175-187.

Fogarty, M.J. 1989. Forecasting yield and abundance of exploited invertebrates. In: J.F. Caddy, Ed. Marine invertebrate fisheries: their assessment and management. New York: John Wiley & Sons, Inc., pp. 701-724.

Gentile, J.H., S.M. Gentile, N.G. Hairston Jr., and B.K. Sullivan. 1982. The use of life tables for evaluating the chronic toxicity of pollutants to *Mysidopsis bahia*. Hydrobiologia 93:179-187.

Gentile, J.H., G.G. Pesch, K.J. Scott, W.R. Munns, and W. Nelson. 1990. Bioassessment methods for determining the hazards of dredged material disposal in the marine environment. In: S.S. Sandhu, W.R. Lower, F.J. de Serres, W.A. Suk, and R.R. Tice, eds. In situ evaluation of biological hazards of environmental pollutants. New York: Plenum Press, pp. 31-47.

Ginzburg, L.R., L.B. Slobodkin, K. Johnson, and A.G. Bindman. 1982. Quasi-extinction probabilities as a measure of impact on population growth. Risk Analysis 2(3):171-181.

Hansen, D.J. 1984. Utility of toxicity tests to measure effects of substances on marine organisms. In: H. White, Ed. Meaningful measures of marine pollution. College Park, MD: University of Maryland Press, pp. 73-88.

Hattis, D. and J.A. Smith, Jr. 1986. What's wrong with quantitative risk assessment? In: R.F. Almeder, and J.M. Humber, eds. Biomedical ethics reviews. Clifton, NJ: The Humana Press, pp. 57-105.

Kenaga, E.E. 1982. Predictability of chronic toxicity from acute toxicity of chemicals in fish and aquatic invertebrates. Environ. Toxicol. Chem. 1:347-358.

Levin, L.A., H. Caswell, K.D. Departra, and E.L. Creed. 1987. The lifetable consequences of larval development mode: an intraspecific comparison of planktotrophy and lecithotrophy. Ecology 68: 1877-1886.

Mayer, F.L. Jr., S. Mayer, and M.R. Ellersieck. 1986. Relation of survival to other endpoints in chronic toxicity tests with fish. Environ. Toxicol. Chem. 5:737-748.

Mehrle, P.M. and F.L. Mayer. 1980. Clinical tests in aquatic toxicology: state of the art. Environ. Health Perspect. 34:139-143.

National Research Council. 1983. Risk assessment in the federal government: managing the process. Washington, DC: National Academy Press.

Society of Environmental Toxicology and Chemistry (SETAC). 1987. Research priorities in environmental risk assessment. Washington, DC.

Slooff, W., J.H. Canton, and J.L.M. Hermens. 1983. Comparison on the susceptibility of 22 freshwater species to 15 chemical compounds. I. (Sub)acute toxicity tests. Aquat. Toxicol. 4:113-128.

Stephan, C.E., and J.W. Rodgers. 1985. Advantages of using regression analysis to calculate results of chronic toxicity tests. In: R.C. Bahner and D.J. Hansen, eds. Aquatic toxicology and hazard assessment: eighth symposium. ASTM Special Publication 89. Philadelphia, PA: American Society of Testing Materials, pp. 328-338.

Suter, G.W. II. 1989. Ecological endpoints. In: Ecological assessment of hazardous waste sites: a field and laboratory reference. EPA/600/3-89/013. Corvallis, OR: U.S. EPA Environmental Research Laboratory, Corvallis.

Suter, G.W. II. 1990. Endpoints for regional ecological risk assessments. Environ. Man. 14(1):9-23.

Suter, G.W. II, and A.E. Rosen. 1988. Comparative toxicology for risk assessment of marine fishes and crustaceans. Environ. Sci. Technol. 22(5):548-556.

Suter, G.W. II, D.S. Vaughan, and R.H. Gardner. 1983. Risk assessment by analysis of extrapolation error: a demonstration for effects of pollutants on fish. Environ. Toxicol. Chem. 2:369-378.

Suter, G.W. II, L.W. Barnthouse, J.E. Breck, R.H. Gardner, and R.V. O'Neill. 1985. Extrapolating from the laboratory to the field: how uncertain are you? In: R.D. Cardwell, R. Purdy, and R.C. Hahner, eds. Aquatic toxicology and hazard assessment: seventh symposium. ASTM STP 854. Philadelphia, PA: American Society for Testing and Materials, pp. 400-413.

Suter, G.W. II, A.E. Rosen, and E. Linder. 1986. Analysis of extrapolation error. In: L.W. Barnthouse, G.W. Suter II, A.M. Bartell, J.J. Beauchamp, R.H. Gardner, E. Linder, R.V. O'Neill, and A.E. Rosen, eds. User's manual for ecological risk assessment. Oak Ridge, TN: Oak Ridge National Laboratory.

Suter, G.W. II, A.E. Rosen, E. Linder, and D.F. Parkhurst. 1987. Endpoints for responses of fish to chronic toxic exposures. Environ. Toxicol. Chem. 6:793-809.

Tucker, R.K. and J.S. Leitzke. 1979. Comparative toxicology of insecticides for vertebrate wildlife and fish. Pharmacol. Ther. 6:167-220.

U.S. Environmental Protection Agency. 1986a. Guidelines for Carcinogen Risk Assessment. Fed. Reg. 51:33992-34003. September 24.

U.S. Environmental Protection Agency. 1986b. Guidelines for Mutagenicity Risk Assessment. Fed. Reg. 51:34006-34012. September 24.

U.S. Environmental Protection Agency. 1986c. Guidelines for the Health Risk Assessment of Chemical Mixtures. Fed. Reg. 51:34014-34025. September 24.

U.S. Environmental Protection Agency. 1986d. Guidelines for the Health Assessment of Suspect Developmental Toxicants. Fed. Reg. 51:34028-34040. September 24.

U.S. Environmental Protection Agency. 1986e. Guidelines for Exposure Assessment. Fed. Reg. 51:34042-34054. September 24.

U.S. Environmental Protection Agency. 1988a. Proposed Guidelines for Assessing Male Reproductive Risk and Request for Comments. Fed. Reg. 53:24850-24869. June 30.

U.S. Environmental Protection Agency. 1988b. Proposed Guidelines for Assessing Female Reproductive Risk; Notice. Fed. Reg. 53:24834-24847. June 30.

U.S. Environmental Protection Agency. 1988c. Proposed Guidelines for Exposure-Related Measurements and Request for Comments; Notice. Fed. Reg. 53:48830-48853. December 2.

U.S. Environmental Protection Agency. 1988d. Review of ecological risk assessment methods. EPA 230/10-88-041. Washington, DC: U.S. EPA Office of Policy Analysis, Office of Policy, Planning, and Evaluation.

U.S. Environmental Protection Agency. 1988e. Appendix B: Strategies for exposure assessment research. Report of the Exposure Assessment Subcommittee, Research Strategies Committee, Science Advisory Board. SAB-EC-88-040B. Washington, DC.

U.S. Environmental Protection Agency. 1989. Proposed Amendments to the Guidelines for the Health Assessment of Suspect Developmental Toxicants; Request for Comments; Notice. Fed. Reg. 54:9386-9403. March 6.

U.S. Environmental Protection Agency. 1990a. Reducing risk: setting priorities and strategies for environmental protection. Report of the Relative Risk Reduction Strategies Committee, Science Advisory Board. SAB-EC-90-021. Washington, DC.

U.S. Environmental Protection Agency. 1990b. The Report of the Ecology and Welfare Subcommittee, relative risk reduction project: reducing risk; Appendix A. Report of the Relative Risk Reduction Strategies Committee, Science Advisory Board. SAB-EC-90-021A. Washington, DC.

Weinberg, J.R. 1985. Factors regulating population dynamics of the marine bivalve *Gemma gemma*: intraspecific competition and salinity. Mar. Biol. 86:173-182.

Weinberg, J.R., H. Caswell, and R.B. Whitlatch. 1986. Demographic importance of ecological interactions: how much do statistics tell us? Mar. Biol. 93:305-310.

Widdows, J. 1982. Field measurement of the biological impacts of pollutants. In: J.C. Su and T.C. Jung, eds. Proceeding of a pacific regional workshop on the assimilative capacity of the oceans for man's wastes. Taipei, China: Scope/ICSU Academia Sinica, pp. 111-129.

Yount, J.D. and G.J. Niemi, eds. 1990. Recovery of lotic communities and ecosystems following disturbance - a narrative review of case studies. Environmental Management Vol. 14, No. 5. New York, NY: Springer-Verlag. In press.

Zajac, R.N. and R.B. Whitlach. 1989. Natural and disturbance induced demographic variation in an infaunal polychaete, *Nephtys incisa*. Mar. Ecol. Progr. Ser.

SECTION THREE
MEETING SYNOPSES

3.1 STATE AND FEDERAL AGENCY REPRESENTATIVES

Individuals from numerous state and federal agencies met to discuss issues related to the use of ecological risk assessments within their organizations. Although this was not meant to be a comprehensive review of state and federal programs, the individuals attending these meetings represented a wide range of approaches to ecological risk assessment. Federal agency representatives answered specific questions related to their use of ecological risk assessment techniques, while the state representatives presented their programs using a less structured format. The personal opinions expressed by these individuals do not necessarily reflect the views or opinions of their agencies. A general review of the programs from both state and federal agencies is presented in this section; more detailed summaries of individual presentations may be found in Appendices E and F.

The types of ecological assessments conducted by the state and federal agencies can be grouped in four categories:

- Predictive hazard assessments. These studies compare the estimated environmental exposure and potential effects of new compounds, as is done by EPA's Office of Toxic Substances. The U.S. Food and Drug Administration (FDA) also conducts this type of assessment.

- Predictive impact assessments. Many state and federal agencies conduct studies to determine the potential ecological impact of anticipated actions. Predictive impact assessments are conducted under federal laws such as the Clean Water Act and the National Environmental Policy Act. Regulatory authorities frequently base permitting actions on the results of impact assessments, including discharge permits under the Clean Water Act and dredging permits issued by the Army Corps of Engineers.

- Retrospective impact assessments. These studies are commonly required at Superfund sites, where the objective is to determine whether adverse ecological impacts have occurred as a result of past hazardous waste disposal practices. Representatives from New Jersey and several federal agencies described their activities in this area.

- Monitoring. Both NOAA and the U.S. Fish and Wildlife Service (FWS) conduct monitoring studies to detect environmental trends, most frequently involving chemical residues in biota.

The methods used in these studies frequently involve some variation of the NAS risk assessment paradigm, although actual probabilities of effect generally are not determined. A wide range of techniques have been used to estimate hazard to organisms, from simple literature reviews to direct measurements, field observations, and models. For example, Ohio has developed an effluent discharge permit program that includes established effluent biocriteria, field surveys of potentially impacted aquatic communities, and laboratory effluent testing. The "Apparent Effects Threshold" method used by Washington State integrates aspects of chemical exposure and toxicity bioassays to determine the hazard to aquatic biota of chemicals in sediments.

Participants mentioned many factors as important in selecting endpoints for ecological effects assessments. In addition to ecological relevance, sensitivity, etc., several individuals discussed the need to consider such values as recreational, commercial, economic, or social importance, and one state indicated that endpoints should either have direct significance to humans or be indirect indicators of an effect of significance to humans. Some state and federal agencies specifically include considerations of habitat alteration in their evaluations, and two states consider the potential for ecosystem recovery in evaluating site clean-up plans.

State and federal agency representatives also described the use of qualitative and quantitative methods for evaluating uncertainty in their ecological assessments. Some agencies use qualitative assessments that rely heavily on professional judgment, while others use numerical uncertainty factors. One state (New Jersey) is using a technique developed by Suter et al. (1985) to quantify the uncertainty associated with interspecies extrapolations of toxicity data.

The state representatives mentioned a wide range of topics that they would like to see addressed in ecological risk assessment guidelines, including sediment toxicity, chemical mixtures, bioavailability and bioaccumulation factors, and appropriate aquatic and terrestrial surrogate species. One representative recommended that the guidelines include multimedia exposures and exposure and effects at all trophic levels. Some participants suggested that the guidelines provide estimates for clean-up goals, baseline analyses, and analysis of remediation alternatives. Other recommendations included keeping the guidelines flexible, and ensuring that the costs of implementation are considered. One person suggested including an evaluation of effectiveness with any proposed risk assessment methods, but some considered this to be inappropriate. Some participants expressed concern that new EPA guidelines might have implications for state agencies, possibly effecting existing programs and creating additional responsibilities without a commensurate increase in resources.

Personnel from other federal agencies discussed the possible scope and content of the ecological risk assessment guidelines at length. Some suggested that guidelines should be prepared for both predictive and retrospective studies. Participants agreed in general that extrapolations to population- and community-level ecological effects would be difficult, but everyone acknowledged the usefulness of community effects assessments. They also suggested that the guidelines should indicate the minimum standards required for an assessment to be considered acceptable. The participants expressed considerable support for the guidelines development effort, as well as an interest in continued association with the guidelines development process to help EPA produce broad, generic ecological risk assessment guidance.

3.2 SCIENCE ADVISORY BOARD (CONSULTATIVE MEETING)

The Ecological Risk Consultative Group, a subcommittee of the Ecological Processes and Effects Committee of EPA's Science Advisory Board (SAB), discussed issues surrounding the development of ecological risk assessment guidelines. The SAB encouraged EPA to develop such guidelines and identified a number of important issues. Minutes of the meeting are provided in Appendix G.

SAB members expressed some concern that the state of scientific knowledge may be inadequate to support the full development of ecological risk assessment guidelines, but acknowledged that the guidelines would help identify important issues and research needs and could be revised to incorporate new knowledge as it is obtained. Some participants suggested that both qualitative and quantitative methods could be included in the guidelines, although there was some disagreement on this point. Critical parts of the ecological risk assessment process that should be addressed include identifying and selecting appropriate endpoints, and identifying and quantifying uncertainties. The SAB agreed with the view expressed at the federal agency meeting that initial EPA efforts be directed toward developing general guidance for conducting ecological risk assessments. The SAB suggested that EPA should:

- Develop a preliminary broad outline to describe the entire ecological risk assessment process.
- Develop detailed, subject-specific guidelines that include assessments of both plant and animal populations.
- Delay the more difficult task of writing guidelines for community- or ecosystem-level effects until additional research and field validation information is available.

3.3 REFERENCES

Suter, G.W., II, L.W. Barnthouse, J.E. Breck, R.H. Gardner, and R.V. O'Neill. 1985. Extrapolating from the laboratory to the field: how uncertain are you? In: R.D. Cardwell, R. Purdy, and R.C. Hahner, eds. Aquatic toxicology and hazard assessment: seventh symposium. ASTM STP 854. Philadelphia, PA: American Society for Testing and Materials, pp. 400-413.

APPENDICES

These minutes were prepared by Eastern Research Group, a U.S. Environmental Protection Agency (EPA) contractor, as a general record of discussions during each meeting. As requested by EPA, the minutes capture the main points of each scheduled presentation, as well as highlights from the general discussion; the minutes are not a complete record of all details discussed, nor do they embellish, interpret, or enlarge upon matters that were incomplete or unclear. The minutes will be used by the Risk Assessment Forum as a basis for additional study and work on the ecological risk issues.

Handouts and other materials submitted by participants (listed in Appendix H) are available in the EPA Headquarters Library, Public Information Reference Unit, 401 M Street, SW, Washington, DC 20460.

APPENDIX A

U.S. ENVIRONMENTAL PROTECTION AGENCY
Risk Assessment Forum Colloquium Series on Ecological Risk Assessment

The National Academy of Sciences Risk Assessment Paradigm

March 26, 1990

Introduction

This report summarizes the discussion at the first colloquium, held March 26, 1990, in Washington, DC in the Washington Information Center, 401 M Street, SW. Three experts in the field of ecological risk assessment were invited to discuss possible approaches to ecological risk assessment in light of the National Academy of Sciences (NAS) paradigm, which EPA has used for many years in human risk assessment for cancer and other adverse human health effects. The scheme consists of four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. The Guidelines Work Group hoped to gain some insight as to whether the existing scheme is appropriate or adequate for ecological risk assessments, and whether new definitions or other modifications are needed. The group asked the speakers to address the following issues:

- How can the Guidelines best present the elements of ecological risk assessment?
- Are there types of ecological assessments that do not fit into the NAS paradigm? How can they best be handled?
- What modifications to the NAS scheme will be needed to address stresses other than chemical exposure?

Following is a summary of the presentations and discussion at the meeting, which was chaired by Dr. Jerry Stober of EPA Region 4. Attachment A contains the agenda and list of invited attendees; references and handouts from the speakers are listed in Appendix H.

Background

Bill Wood, Risk Assessment Forum

Dr. Wood began by explaining the purpose of the RAF colloquium series, which is to provide support for the development of a new set of ecological risk assessment guidelines. He explained that the Risk Assessment Forum falls under the direction of the Risk Assessment Council, which answers directly to the EPA Administrator. The RAF is a group of 18 EPA scientists representing different programs in the Agency, and develops consensus from within EPA on risk assessment issues. The Forum also provides oversight to guideline workgroups.

In 1983, the National Academy of Sciences reviewed risk assessment as it was performed in various federal agencies at that time, and developed the NAS "Red Book," which describes the risk assessment process and defines terms used. NAS also made recommendations to the federal agencies on carrying out risk assessments. One of the recommendations to EPA was to develop "inference guidelines" that describe acceptable approaches, provide guidance on new or alternative approaches, and list sources for information on the topic of concern.

In response, EPA initiated the guideline development process, which incorporates 2 to 3 years of initial development, intra and inter-agency review, and final acceptance by the Administrator. The final, published guidelines are updated often to incorporate new information. The guidelines provide scientific policy that ensures consistency across the Agency, promotes quality in risk assessments, and supplies information to the public and other scientists. Guidelines stop at the risk characterization step in the EPA risk assessment process; risk management instruction is not provided. Dr. Wood stressed that guidelines are not step-by-step cookbooks, strict rulebooks, or textbooks - guidelines assume a fundamental knowledge of the subject matter. Dr. Wood stressed that since these will be the first ecological risk assessment guidelines for the agency, the guidelines writers will need to place emphasis on developing a consistent set of terms and definitions. He added that not only the risk assessors, but also risk managers would need more specific information on ecology, so the ecological risk assessment guidelines should stress risk characterization more than other guidelines have.

NRC Committee on Risk Assessment Methods, Ecological Risk Assessment Plans

Lawrence Barnthouse, Oak Ridge National Laboratory

Dr. Barnthouse summarized the activities to date of the National Research Council (NRC) Standing Committee on Risk Assessment Methods (CRAM), which is reassessing the NAS paradigm. Unlike most NRC committees, CRAM will last for at least 3 years. The committee will assess the basis of the NAS paradigm, review the inference assumptions, regulatory uses, and research needs in risk assessment to determine whether it should be updated and revised. The committee hopes to move the Red Book away from policy, and more toward scientific statements. It has begun to develop a list of seven topics, or issues, to be addressed in subcommittees; the subcommittees will produce focus papers leading to workshops. In the end, each group will draft a subcommittee report to CRAM. These reports will:

- Relate major problems to the existing paradigm. Several problems identified to date include pesticides and toxic chemical regulation, water pollution control, and regional air pollution, and some non-chemical effects on the environment.
- Define data and methods appropriate for addressing each problem.
- Evaluate adequacy of existing data and methods.

CRAM has already identified ecological risk assessment and a subcommittee is currently working to identify issues to be addressed in the focus papers. The subcommittee has agreed that the best way to proceed with the issue of ecological risk assessment is to forge ahead, and "not dwell on the old." Dr. Barnthouse listed some tentative target dates for the various aspects of this project. The ecological risk assessment subcommittee will invite more environmental scientists to join their group by the end of March, 1990; in May, the group will develop a prospectus; the focus papers will be commissioned by July 1990; a workshop will take place in November; a first draft of the subcommittee report will be done in January, 1991, and the final report is scheduled for completion by July of 1991.

Dr. Barnthouse concluded by saying that if the NAS paradigm is interpreted loosely, as it should be, ecological risk assessment can fit into the existing scheme. For example, determining the target organism in ecological risk assessment can be roughly equated to finding the target organ in cancer risk assessment. He reminded the group that risk characterization, including the description of uncertainty, does not have to be quantitative, and that risk assessors often read more into the NAS Red Book than is actually there. Dr. Barnthouse sees the ecological and human risk assessment schemes as parallel, but not necessarily interchangeable.

Ecological Risk Assessment: Factors that Determine Ecological Responses to Stress

Mark Harwell, Cornell Ecosystems Research Center

Dr. Harwell began his presentation by agreeing that ecological risk assessment could fit into the NAS paradigm, but added that he wouldn't choose that scheme if it is possible to start from the beginning with the guidelines. There are too many issues specific to ecological assessment that would need to be addressed if the NAS is used, he added.

Dr. Harwell led the group through a detailed outline of factors that determine ecological responses to stress. All anthropogenic activity causes change, he explained, and the degree to which the ecosystem is affected depends on many factors, for example:

- The frequency and duration of the exposure, the fate and transport of the agent through the ecosystem, and the feedback within the biota dictate the degree of stress placed on the ecosystem.
- Spatial (including whether there is another affected habitat nearby), temporal, and organizational scale all contribute to how the ecosystem responds to the change. Characterizing the response depends on identifying the endpoint of concern, and recognizing the indicators that show that endpoint has been affected.
- The ecosystem's ability to recover from the stress is an important factor. If a change is reversible or easily mitigated, then it may not be as serious a threat as it may seem at first. The scale and intensity of the effect is important as well.

Decision-making in ecological risk assessment requires some knowledge of the ecosystem being affected, both to identify endpoints of concern to humans and to choose indicators of effect on those endpoints. Often there is not only one endpoint, but a whole suite of effects that must be evaluated. There must be a set of criteria for choice among the different endpoints and indicators, explained Dr. Harwell. Risk assessors need to separate out the endpoints that are meaningful to humans, and then communicate that concern to the risk manager. Uncertainties in the final risk assessment incorporate variability from the data-gathering stages (defined as intrinsic uncertainty) as well as from the assumptions used in final extrapolation across ecosystems or endpoints (uncertainties resulting from lack of knowledge or data gaps). He stressed, however, that, even in the presence of uncertainty, decisions could be made - uncertainty does not mean there is no answer to the problem.

In 1987, the EPA Science Advisory Board produced an "Unfinished Business" report called "A Comparative Assessment of Environmental Problems" that listed risks to be addressed in four areas: human cancer, human noncancer, ecological, and welfare. That project has been taken up again. A workgroup has identified 30 problem areas, ranging from air pollution to contaminated sludge, that will be ranked according to the type of stress and the response produced, using much the same scheme as described above. Preliminary work points to non-chemical issues (such as global warming, ozone depletion, and habitat alteration) as the most important problems facing the United States today. Dr. Harwell pointed out that these issues dominate the field of ecology, and should be addressed in the EPA guidelines.

Dr. Harwell concluded his presentation with an overview of some factors to be considered while developing the ecological risk assessment guidelines:

- Improved methods for predicting ecological responses to stress are needed. Try to expand from laboratory testing to modeling and field research.
- Even relative predictions, or rankings of the endpoints and risks, can be helpful to risk managers.
- Guidelines and risk decisions are "adaptive management" tools - they will be back again for review and revision, so all answers do not have to be answered on this round.
- Use sensitivity analysis of environmental components to develop a hierarchy of indicators.
- Develop a tiered approach to testing.

Perspective on Ecological Risk Assessment Using the NAS Paradigm

Glen Suter, Oak Ridge National Laboratory

Dr. Suter defined a paradigm as "the way people think about a problem." He proceeded to describe two types of paradigms that could be used in ecological risk assessment, and how they fit into the NAS scheme.

The first paradigm, predictive risk assessment, deals with proposed actions. It predicts the risk associated with a new chemical, new source, or possible accident. In the first step, which corresponds to the hazard identification portion of the NAS scheme, the risk assessor chooses the endpoint of concern (either *diverse*, dealing directly with the population affected, or *hierarchical* endpoints, dealing with the organizational level affected); describes the habitat (perhaps using reference or generic sites); and obtains source terms (such as release rate, disturbance rate, temporal and spatial information). To make sure the endpoint predicted is logical in light of the agent and its physical and chemical characteristics, the endpoints are chosen according to a set of criteria. Dr. Suter suggested that, when choosing endpoints, the risk assessor should first concentrate on those that are most common and readily measured with current technology.

Exposure assessment is performed in this scheme as well as in the NAS paradigm; however, effects assessment takes the place of dose-response assessment. Effects assessment uses "effects models" that predict the effect of the agent on the chosen endpoint over time, incorporating information on population and ecosystem processes, as well as information on the chosen endpoint's characteristics. The models can include multiple species and habitats to produce an estimate of the overall effect. Integration of the data collected in the effects and exposure assessment phases is equivalent to the risk characterization step in the NAS scheme. This final integration step must show a causal relationship between the source and effect. Finally, this information is passed on to the risk manager, who can feed information back to the beginning of the process, and perhaps ask for testing on a different endpoint or habitat.

The second method for ecological risk assessment is retrospective assessment. In general, with this assessment scheme, the risk assessor starts with a known source (like an oil spill), exposure, or effect, and assesses the potential risk. (In retrospective assessments, there is no need to define the habitat, but it must be delineated.) Unlike the predictive risk assessment, which follows from source to the final characterization, there is no consistent step-by-step way to do a retrospective assessment because the starting point is always different, explained Dr. Suter. The steps in the assessment feed back to the assumed cause and effect, and the steps in that proof are interrelated: the source will produce an exposure only if the environmental factors are just right, and that exposure produces an effect only if susceptibility is there.

There are three methods of retrospective ecological risk assessment: epidemiology, toxicity testing, and modeling.

Epidemiological assessment identifies an effect as real and determines the magnitude of the effect, helps to identify the cause, and predicts the ultimate consequences. Dr. Suter suggested that this method is the most applicable to ecological risk assessment, and outlined the steps involved:

- To establish whether an effect is real, the risk assessor must consider whether the presumed effect is due to natural variability. The assessor cannot simply compare one site to another and call any differences "effects;" the assessor must decide what is "normal" for that particular site and compare the differences, or limit the chosen endpoints to those that are "genuinely aberrant."

- To determine the cause of the observed effect, the assessor can use traditional methods for proving causality, for example, Koch's postulates. These postulates, used in epidemiological studies, list a number of criteria that must be met before a causal relationship can be assumed. Koch's postulates, however, may be difficult to carry through an ecological assessment, and determining the cause becomes a weight-of-evidence problem.

- To identify and determine the magnitude of the ultimate effects, the risk assessor must use models if there are no true replicates for the site. These models can predict recovery, assuming the endpoint is reversible. The assessor may need to use toxicity tests to extrapolate beyond the current conditions, and may even need to apply a model to predict the recovery process.

Toxicity-based retrospective risk assessments are used when field measurements are impractical. Effluent, media, and ambient tests are correlated with effects observed in the field. If no effects are observed, the probability of false negatives should be calculated - perhaps more sensitive species exist that were not used in laboratory tests. Diagnostic markers also fall under this category.

The last type of retrospective assessments, model-based risk assessments, resemble predictive assessments in that they start from the beginning of the paradigm, with the source, and move through step by step to determine the effect. This method is used when tests and field measurements are impossible.

The NAS paradigm forces retrospective studies into a predictive scheme. Dr. Suter recommended site- or case-specific epidemiology studies as the best alternative for ecological risk assessment. Such studies are more true-to-life. They are also easier to perform than human risk assessments because more organisms are available; the use of surrogate species is an option; and indicators are easier to identify.

Discussion

Following the presentations, the group discussed certain issues in detail:

- How can the guidelines balance the consideration of endpoints of concern to humans with endpoints of ecological concern?
- Where does the habitat fit into the NAS paradigm?
- Is there a set of "tools" already in place for carrying out ecological risk assessments? What type of data base is needed? Is ecological risk assessment possible with the current body of knowledge?

Endpoints of Human Concern vs. Endpoints of Ecological Concern

The group discussed whether the guidelines should recommend a hierarchy of endpoints, and if so, how that hierarchy should be set up. Dr. Harwell proposed a hierarchy according to the endpoint's impact on humans. He said that humans perceive different things as important. The last of a species of minnow, for example, may not be as important to humans as the last blue whale. Some participants thought that considering whether endpoints were of concern to humans is a risk management issue which should not to be considered in the risk assessment process. Such "pre-judging" could color the information-gathering stages of the assessment. Others disagreed. A participant stated that it is not a political decision, but rather a scientific one at the beginning, when choosing the endpoint. But not all regions and agencies have the same priorities, another argued, so the endpoint cannot be chosen for them.

Several participants thought that the risk managers should be given a set of decision criteria to select from a suite of ecological endpoints identified by the risk assessor. Dr. Harwell thought the risk manager is too far down in the process. The real question is, "what are the things in the system we care about, and what do we measure to monitor effects on them?" he added. Dr. Suter expressed doubt that the scientist/risk assessor had the objectivity to make such decisions. However, Drs. Harwell and Barnthouse thought that information is available, and the assessment could be done with the available information. They also thought that almost any endpoint could, and should, be related back to effects on humans, in words that the layperson can understand.

The group agreed that perhaps the risk assessor can start with a long list of possible endpoints, then narrow it down as part of the assessment: "for each class of risk assessment, there are certain endpoints or measurements that are more relevant."

Where Does Habitat Fit Into the NAS Paradigm?

There was some discussion of the definition of habitat versus ecosystem. The habitat, it was decided, is where the organism lives and what the organism needs in its surroundings. An ecosystem is the whole of a range of habitats. Some participants wondered whether EPA should avoid trying to evaluate habitat on its own, as it is a "multi-agency problem." They thought that the Agency could somehow coordinate with the Fish and Wildlife Service, which performs numerous habitat surveys regularly, and has developed a Habitat Evaluation Procedure (HEP) for that purpose. HEP is used more for mitigation, and may not provide enough information for a risk assessment, however.

Several participants did not think that EPA should avoid the issue of habitat characterization. A participant pointed out that EPA is considering habitat alteration as an endpoint, and cannot pass the issue off onto another agency. Habitat alteration is also a stressor, added Dr. Suter. He thought that something like HEP could be used to determine the target organisms' needs, but not necessarily serve as information on habitat change as an endpoint. Another participant added that the Fish and Wildlife Service thought HEP could be useful in more long-term assessments.

One participant asked if habitat had a parallel in human risk assessment. This is what sets ecological risk assessment apart, explained Dr. Harwell. Dr. Suter agreed. It was suggested that a habitat evaluation should come as one of the first steps in the risk assessment, then would serve as a check at all points in the risk assessment to keep the assessment on a logical plane.

Finally, one participant asked the guidelines workgroups not to forget to consider effects on plants an endpoint, rather than a stressor or change in habitat for animals and birds.

Is There a Set of "Tools" Already In Place for Carrying Out Ecological Risk Assessments?

Dr. Stober explained that in the Regions, he does not often see ecological risk assessment incorporated into Environmental Impact Statements, even when requested. He thought that if the ecological risk assessment guidelines incorporated toxicity tests that are familiar, more people would be willing to incorporate it into the process. Some present were concerned that the resulting guidelines may be too simple, and may not incorporate all of the current knowledge. A participant added, "a little knowledge is a dangerous thing," and asked if the guidelines wouldn't become a short cut or "cookbook" for those doing the testing. Another participant suggested using case studies as examples in the text. Dr. Stober agreed that would be helpful.

The group agreed that the best solution would be to list types of tests, rather than specific tests, in the guidelines. This leaves room for new developments, and, by supplying just enough information on the process, and references to guidance manuals and reference books, the risk assessor who is not familiar with ecology will be forced to seek out someone who is.

ATTACHMENT A

Agenda, Speaker List

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

THE NAS RISK ASSESSMENT PARADIGM

Washington Information Center
401 M Street, SW
Washington, DC 20460

March 26, 1990

Agenda

10:00am	Opening Remarks - William Wood, Risk Assessment Forum
10:15am	Activities of the NAS/Ecological Risk Topic Group - Lawrence Barnthouse, Oak Ridge National Laboratory, NRC Committee on Risk Assessment Methods
10:45am	Applicability of the NAS Paradigm to Ecological Risk Assessment - Mark Harwell, Cornell University Ecosystems Research Center
11:15am	Perspective on the NAS Paradigm - Glenn Suter, Oak Ridge National Laboratory
11:45am	Lunch
1:00pm	Open Discussion
4:45pm	Concluding Remarks - William Wood, Risk Assessment Forum

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

THE NAS RISK ASSESSMENT PARADIGM

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APPENDIX B

U.S. ENVIRONMENTAL PROTECTION AGENCY
Risk Assessment Forum Colloquium Series on Ecological Risk Assessment

Uncertainty Issues in Hazard Assessment

April 30, 1990

Introduction

This report summarizes the discussion at the second colloquium, held April 30, 1990, in Washington, DC in the Washington Information Center, 401 M Street, SW. The discussion focused on methods currently used to extrapolate among species and endpoints, from laboratory to field, and between exposure durations, and the uncertainties associated with these extrapolations. The participants discussed the reliability of the extrapolations themselves and the pros and cons of various extrapolation procedures. The group also considered available data sets, and the role of biomarkers in extrapolations.

Attachment A to this appendix includes the agenda and list of speakers for the meeting; references and handouts supplied by the speakers are listed in Appendix H. Dr. Steve Bradbury, from EPA's Environmental Research Laboratory in Duluth, Minnesota, chaired the meeting.

Welcome

Steve Bradbury, U.S. EPA Environmental Research Laboratory, Duluth

Dr. Bradbury provided an overview of the uncertainties involved in hazard assessment. He explained that the purpose of the meeting was to assess the uncertainty involved in hazard assessment extrapolations: from individual-level to population-level to community-level, and, finally, to ecosystem-level effects for aquatic and terrestrial systems. For example, EPA's Office of Toxic Substances and Office of Pesticides Programs start from the individual level and make predictions at the community and ecosystem levels, whereas the Superfund Office and some state programs estimate potential effects on individuals from community-level effects observed in on-site studies. He pointed out that the group should consider not only the uncertainties associated with extrapolation from one level to the next, but also the interconnections between these levels of biological organization: how does information determined at one level (e.g., an LC_{50}) apply to assessments at other levels? While the group will consider individual level assessments, they must keep in mind as the discussion progresses and information is gathered, that the assessments will be used implicitly or explicitly to predict or explain hazard at the population or community level. There is also uncertainty in extrapolating hazard assessment data between levels of organization (e.g., species to species, endpoint to endpoint). Finally, how does laboratory testing relate to realities in the field?

Endpoint to Endpoint and Exposure Duration Extrapolations

Foster Mayer, ERL-Gulf Breeze, Florida

Dr. Mayer described a study that compared the relative sensitivity of several endpoints. He then discussed ways of predicting chronic effects from acute data, and gave a specific example that compared laboratory predictions and field results.

Dr. Mayer discussed a series of toxicity studies conducted by the U.S. Fish and Wildlife Service in Columbia, Missouri (34 studies on 7 fish species with 28 chemicals). The frequency of numerous endpoints was compiled not only for reproduction, growth, and survival, but also for endpoints not measured as often in fish studies, such as histopathology (both gross and tissue pathology), clinical measures of blood chemistry and vertebral abnormalities, disease susceptibility, and behavioral measurements. The researchers reanalyzed and re-categorized the data for internal consistency, and performed a univariate analysis of the ratios of endpoints and percent response.

From this analysis, survival was shown to be more sensitive than all the other measured endpoints, except reproduction. Reproductive effects were the most consistent. Even smoltification, usually considered a sensitive endpoint, was less sensitive than survival. Dr. Suter has conducted a similar mathematical comparisons, and his findings have reenforced the finding that survival is the most sensitive endpoint in most cases. He has also extended the analysis to compare percent inhibition in the population. Survival is also the most cost- and labor-efficient of the endpoints studied. The finding of reproductive effects is the only endpoint that could be better for toxicity tests; however Dr. Mayer did not recommend requiring full life-cycle tests since less than 10 percent of chemicals pose a reproductive threat or an impairment worse than survival tests indicate. He pointed out that biochemical measures do not usually result in significant adverse effects, although they may seem as sensitive as survival or reproduction at the outset.

Most techniques for extrapolating from acute to chronic effects incorporate ratios, application factors, or other estimates, but do not incorporate predictions. Traditional acute-to-chronic ratios result in a factor to extrapolate to chronic effect levels. The disadvantages to this method include:

- Only one point in time is incorporated by an acute LC_{50} value.
- Different endpoints may be compared between acute and chronic tests.
- Different degrees of response are compared: 50 percent lethality for LC_{50} values, and no effect for chronic endpoints.

Dr. Mayer suggested using time intervals (a plot of LC0 at time of exposure vs. 1/time) to predict chronic lethality (infinite LC0, or at the y-intercept of the plot) from acute data.

He also suggested that survival to growth extrapolations are the most reliable. He has used acute data to estimate chronic toxicity, then estimated a no effect level for growth.

Finally, he described field studies performed in Florida and South Carolina. The researchers compared the effects from pesticide runoff observed in the field with estimated mortality from on-site biomonitoring and effects predicted by laboratory tests. These tests included a standard LC_{50} test, a single-pulse (or dose) LC_{50}, and a multiple-pulse LC_{50} value. The multiple-pulse exposure corresponded most closely to observed effects in the field exposures. The conclusions drawn from those studies include:

- Exposure-response relationships were similar in the laboratory and the field.

- Laboratory toxicity tests used worst-case exposure scenarios.
- Tidal creeks that had seasonal fish kills showed effects not only on the abundance and size of fish, but also on bird populations.
- Communities of estuarine biota appeared unaffected by chemicals that did not affect caged resident species.
- Communities of benthic organisms appeared unaffected by contaminated sediment that elicited no toxic response in the laboratory.
- The standard 96-hour LC_{50} values in the laboratory were the same as the multiple-dose LC_{50} values.

When asked, Dr. Mayer recommended against using survival data to predict anything but growth. He stressed again that what uncertainty really comes down to is "repeatability of accuracy."

Species (and other) Extrapolations in Aquatic (and other) Systems

Glenn Suter, Oak Ridge National Laboratory

Dr. Suter stated that statistical methods are inherently better than factor methods because they distinguish between estimation and actual uncertainty.

There are two traditional methods for taxonomic extrapolation:

- Determining the distribution of sensitivities in a community by testing representative species.
- Predicting the sensitivity of taxa from tested species (e.g., for Family or Order from one species).

To determine the sensitivity distribution, one fits a statistical distribution to test endpoint values for species tested with the same chemical, and chooses a percentile to represent the proportion of the community that will be protected. This procedure has been used for National Water Quality Criteria Final Acute Values, although many data are required to calculate acute values for each chemical. Dr. Suter provided two examples: one was a compilation of several distribution curves plotting the log function of survival vs. log LC_{50} for individual fish species; the second was the distribution of the percentage of soil invertebrate species protected related to soil concentrations of cadmium.

A second method for determining sensitivity distribution, which requires fewer data, is the use of a community vs. test species regression model. The response (e.g., LC_{50}s) of all other organisms in the community is regressed against the response of the test species for each chemical. The prediction interval is the area in the plot where 95 percent of the responses fall. This interval is more realistic and important than the confidence interval on the mean.

To predict field response from the response observed in specific tested species, one can use a hierarchy approach, a dose-scaling method, an allometric regression, or another categorization. Dr. Suter outlined how each is carried out and their associated pros and cons:

- Taxonomic Hierarchy. This method is based on the hypothesis that the response of a species to a stress is likely to predict the response of a taxonomically related species. This may fail if the sensitivity fluctuates. The closer the genetic relationship, the greater the predictive capability. This method is least likely to hold for naturally occurring stresses, such as reduced dissolved oxygen, but Dr. Suter has derived equations for extrapolating between taxa of freshwater and marine fish and arthropods that give prediction intervals for the two systems within an order of magnitude.

- Allometric Regression. The effectiveness of this method depends on which regression model is used. Dr. Suter showed a graph comparing least squares and major axis regression modeling; he suggested that major axis regression is more appropriate for ecological measurements, when variance on the x and y axes is equal. This regression technique is commonly used with mammals.

- Dose Scaling. Scaling can be either based on a physical dimension, such as body weight or surface area; or on food consumption, which can be used to convert dietary intakes to equal doses. Allometric regression can also be used for dose scaling. When the endpoint is plotted against the physical dimension that scales dose, the response of a new species can be predicted from that plot's dimensions.

- Other Methods.

    - Time-to-response measurements are more useful than proportion responding values, such as LCs. A one-time LC_{50} does not reveal as much about the situation as a measurement of the response at numerous times.

- Response parameters, such as proportion responding and severity of response, are not as helpful in ecological systems as they could be in human health scenarios. Prediction intervals for extrapolations between life cycles and from individual to population level, however, could be useful. A flow chart developed by Barnthouse, Suter, and Rosen (Environ. Toxicol. Chem., 1990, 9:297-311) shows how a series of extrapolation models can be used to work from seven types of standard toxicological information (from a life-cycle test for the species to physical and chemical properties of the contaminant) to produce the parameters of a population model for fish.

Discussion

One participant asked whether it is reasonable to extrapolate from mortality to reproductive endpoints. Drs. Mayer and Suter explained that any kind of extrapolation can be performed, but one has to be ready to deal with the uncertainty involved. Extrapolating from mortality to reproductive effects would incorporate significant uncertainty.

Another questioner asked why Dr. Suter had advised the group against using the Maximum Acceptable Toxicant Concentration (MATC) value. Dr. Suter explained that the MATC and NOEL incorporate problems in the experimental design and the resultant calculation is only a geometric mean of safe and unsafe concentrations.

One person wondered whether an LC01 value would be a better goal for the ecological risk assessment guidelines than the LC_{50} value, even though the human health program has rejected that value as an option. The speakers agreed that it would be reasonable for the guidelines to recommend finding an LC01.

Toxicity Bioassays and Extrapolation Issues

Ron Preston, U.S. EPA Office of Emergency and Remedial Response

Mr. Preston suggested that the guidelines writers keep the practitioner in mind when considering extrapolation issues. Permit writers often ask how effects observed in one species relate to those species present in a particular stream or lake. He summarized several field-to-lab verification studies performed by EPA. The studies showed that:

- Using 20 percent mortality as the "magic number" for positive toxic response tends to underpredict a stress' actual toxicity.
- False positives were minimal as predicted by the Complex Effluent Toxicity Testing Program results. (This was also the case for marine CETTP predictions.)
- Species richness is a consistent, sensitive endpoint for assessing community effects. Some attendees agreed that decreased taxa diversity is a good measure, easily performed, and very reliable.
- Inter-laboratory results are consistent with these test methods.

Dr. Suter questioned the method for verifying the field predictions. He thought that it should not depend on the number of field stations where agreement is observed, but rather the variance around each station.

Mr. Preston stated that Region III has been trying these tests at Superfund and other hazardous waste sites. They are testing site runoff and leachate and conducting benthic macroinvertebrate surveys from test sites and ambient stations. One participant asked how the species-to-species extrapolations have worked thus far. EPA Region III has found that effects observed with daphnids correspond most readily to community effects.

Open Discussion - Aquatic Issues

Using Assumptions to Carry Out Extrapolations

A participant asked the speakers if they thought the guidelines should outline assumptions to take care of the uncertainty associated with these extrapolations, as the human health risk assessment guidelines do. They stated that the methods they put forth incorporate some assumptions - for example, that one species is representative of others, or that sensitivity is relative. Assumptions should not be used to extrapolate between habitats, but could be incorporated into exposure assessment, stated Dr. Suter. Exposure is the underlying problem, when one is looking for effects based on exposure.

Ongoing Research on Aquatic Plants, Amphibians, and Reptiles

Another participant asked if any research on aquatic plants or amphibians and reptiles is ongoing. Plants have not historically been tested with a consistent protocol, nor tested for consistent endpoints. Relative sensitivities of plants has been scarce. Several researchers have attempted to deduce relative sensitivities of plants. The speakers said that amphibians and reptiles are being studied by others, whose work looks primarily at acute and teratogenic effects in tadpoles.

Using Biomarkers

Another topic of discussion was the use of biomarkers to predict the usual toxic endpoints. How well do they work for extrapolation compared to toxicity testing? Dr. Mayer warned against depending on biomarkers as a most sensitive endpoint. He listed two disadvantages to using biomarkers:

- They cannot be used individually, only in batteries of numerous biomarker assays.

- They must be used to complement standard testing, and are not endpoints in themselves.

He suggested that biomarkers may be helpful in interspecies correlation later, but that they should not be developed as a toxic endpoint. A participant asked if biomarkers could be considered an early warning of toxic effects to come, and as a means to keep contaminants out of the environment in the first place. That participant thought that biocriteria are not sensitive enough, and that biomarkers may fill that gap. Dr. Mayer asserted that not enough of the relationships of biomarkers to other, later toxic effects is known to merit inclusion in the guidelines as a test. He suggested that the 7-day test is much more useful, at least until biomarkers are more developed. Dr. Suter asked if an early warning was really feasible since most of the test sites are already polluted.

95 Percent Protection?

Does 95 percent protection mean 95 percent of the species, 95 percent of the endpoints, or 95 percent of the population? This was a recurring theme at the colloquium. The 95 percent value is used by the Water Quality Criteria program (based on the national guidelines for criteria development). Several participants stated that when 95 percent of the species are protected, then some of the other 5 percent are partially protected, since it is a conservative number. A participant advised the guidelines work group members to consider spelling out their rational for any assumption or uncertainty factor they decide upon.

Uncertainty Factors

There was some disagreement in how (or whether) the guidelines should deal with uncertainty factors. Dr. Suter said that risk assessors should be able to use statistical models intelligently and directly. Dr. Mayer said that one cannot always predict all of the factors that will go into an observed response. Statistically generated uncertainty is not as real as biological uncertainty - we know more than the statistics allow, he added. Dr. Suter suggested that risk assessors should use models when they are available, and he was concerned that our knowledge is not as extensive as Dr. Mayer asserts. He added that the quality of the data that goes into a model is a deciding factor in how well a model works. What about extrapolations from laboratory to field results? Is an uncertainty factor necessary? Dr. Mayer stated that predicting indirect effects is a little more subtle, and probably should incorporate an uncertainty factor. Tests to predict direct effects, on the other hand, are more refined and could be used directly.

What is an Acceptable Data Set?

What kind of guidance should be given for compiling the data set? The speakers stated that the quality of the data depends on the type of experiment. They have not found many data sets that are inconsistent with the norm. The variation found in the data sets available come from the variations in real life. Dr. Suter suggested lumping small, like, high-quality data sets together for risk assessment purposes. Experiments in which the organisms are exposed in unnatural conditions should be avoided.

Avian Extrapolation Issues

Gary Heinz, U.S. Fish and Wildlife Service

Dr. Heinz described the difficulties associated with conducting risk assessments on avian species. The large number of species, the varying physiological characteristics of each, their eating and grooming habits, and their annual and daily migratory practices all make birds difficult to study and to make accurate generalizations. Natural populations are subject to any number of stresses, including habitat destruction or loss, disease, hunting, temperature, and predation. Their secretive habits make them hard to count (live or dead), and thus it is hard to assess population effects. The difference in sensitivity to mortality and reproductive effects can be quite large among species as well. Past research has predicted die-offs through the determination of LC_{50}s and LD_{50}s; studies of reproductive effects have also been helpful in identifying harmful chemicals. Tests for biomarkers and bioindicators have also been developed, but how well these predict significant effects is yet to be determined.

Dr. Heinz provided a personal view of avian risk assessment. He suggested that much can be learned by studying all of the variables mentioned above, but the variability is often difficult to quantify, and not consistent.

He recommended against choosing an arbitrary uncertainty factor, but agreed that some sort of species-to-species extrapolation must be performed. By studying past regulatory decisions, the guidelines work groups may be able to determine where the problem was in the risk assessment. Which chemicals fell through the cracks? Which ones were held back, but were later found safe? This may help to determine how large an uncertainty factor is needed.

Discussion

After listening to Dr. Heinz, some participants wondered whether the avian data base is complete enough to support risk assessments. Although 10 years of effort went into that data base, explained Dr. Heinz, it is small compared the aquatic data base. Techniques for modeling, too, are limited in number. The data base has not been statistically evaluated. Some other gaps in the available data include:

- Insufficient metabolism studies have been conducted to determine the mechanism of effect.
- Physiological studies have been conducted, but too few to relate differing physiology to differences in susceptibility.
- Diet studies to convert diet to dose may be available, but the results have not been compiled. (A participant added that EPA is currently collecting those data, but it will not be available for another year.)

Mammalian Extrapolation Issues

Lorenz Rhomberg, U.S. EPA Office of Research and Development

Dr. Rhomberg described the current discussion between EPA and the Food and Drug Administration (FDA) to agree on a species-to-species scaling factor. The two Agencies differ in their approach to determining cancer risk: EPA uses a dose of mg/kg$^{2/3}$/day, while FDA uses a dose of mg/kg/day. He explained that the dose may be refined to mg/kg$^{3/4}$/day using information from pharmacokinetic data. Does that mean that the uncertainty factor (UF) accounting for species to species extrapolation should be abolished with the use of this conversion factor? This is being discussed within EPA. Dr. Rhomberg suggested possible reasons for using a 10-fold uncertainty factor for extrapolations from animal data to humans. The factor could account for:

- Uncertainty. The variation around the risk value extends from -10 to +10 around the mean. A 10-fold UF protects almost everyone. This is probably most like the wildlife variation, Dr. Rhomberg suggested.
- Correction. Humans are 10 times more sensitive than test animals, so a 10-fold factor must be applied.
- Both. Humans are more sensitive (but not as much as 10 times more sensitive), and there is variation around the mean (but not as much as ±10). A factor of 10 accounts for almost every case.

For noncancer effects, the scaling factor accounts for differences in pharmacokinetics, pharmacodynamics, and sensitivity. Any differences between the species all boil down to differences in the rates of metabolism and excretion.

Dr. Rhomberg then suggested a solution to determining the differences in these rates might be to consider physiological time. When a mouse and a human are compared physiologically and metabolically they vary directly as a function of weight to the *n*th power. The basis of the comparison between species is scale. Because excretion and metabolism are scaled similarly, metabolized dose is proportional to size. Because air, food, and water consumed vary in the same way, parts per million of a contaminant should be equal across species.

Physiological time scaling can work for cancer, he added, because time is considered comparable from mice to humans. Whether a mouse exposed for 5 days to a specific concentration will show the same response as a human exposed for 5 days to a proportional dose depends on the endpoint. He showed some examples of how a repeated dose could be brought to equilibrium in a mouse and human at the same level when physiological time is taken into account.

Discussion

One participant asked how physiological time would apply to birds that have differing levels of cholinesterase reduction while receiving the same dose. Dr. Rhomberg stated that sensitivity is not taken into account in these estimates, and that scaling probably only works on an average - for example, if the differences between species lie only in differing rates, then all of the smaller animals in a field would die first. A participant asked whether this scaling method would work for reproductive effects, and the group decided that it would depend on the interactions involved.

Another attendee asked whether the scaling would work for extrapolations to organisms other than mammals. Dr. Rhomberg cited an example of an extrapolation of a mammal to a skate, which worked quite well when temperature and weight corrections were made. Does it matter that the aquatic tests are conducted with little fish? Dr. Mayer assured the questioner that analysis has been performed to compare fish size, and there is only a small difference in effects, which can be easily corrected for.

Dr. Rhomberg explained that this exercise with physiological time is a first approximation, a systematic way of moving the process forward.

Open Discussion - Terrestrial Issues

The work group members listed several areas where information was needed.

- Mortality of plants as an indirect endpoint, or endpoint in itself. The data base PhytoTox out of ERL-Corvallis may be useful.
- Information regarding soil invertebrates, such as mites and other decomposers. Dr. Suter supplied the work group with a reference.
- Extrapolation from aquatic to terrestrial species. This has been carried out for some vertebrates.
- Taxonomic tests on wildlife similar to those for aquatic species. The U.S. Fish and Wildlife Service has information on deer, etc.
- Weight analysis in aquatic tests. This is being conducted, as an attempt to find out mechanisms of action.

Summary Discussion

A participant asked the speakers where they think the largest uncertainties lie. She pointed out that some factors affect the risk assessment more than pharmacokinetics, such as life cycle, or taxonomic and trophic level. She stressed that these guidelines are in the very early stages of development, and are not ready to be refined. Species-to-species extrapolations will be the biggest uncertainty in ecological risk assessments. She asked how much emphasis should be put onto other factors in the risk assessment. Dr. Suter summarized the results from a study on estuarine species, in which the relative effects of differences in life history and toxicology were compared and found to be minimal. He concluded that the differences between the species and endpoints will dwarf the uncertainty in extrapolating from a minnow to a large fish.

Dr. Bradbury asked the speakers to leave the work group members with some insight on the critical issues to keep in mind, and with information regarding development and verification of the models.

- Dr. Mayer cautioned that the search for the most sensitive endpoint is a moot point. Except in a few cases, where reproduction is more sensitive, survival is the best option. As long as exposure and bioavailability are comparable, the correlation between lab and field results for the aquatic tests is good.

- Dr. Suter congratulated EPA on its consideration of ecological risk assessment, and asked that the group consider models that extrapolate from one expression of toxicity to another. He repeated that statistical models are most appropriate for the extrapolation, as not enough is known about biological mechanisms to pinpoint the uncertainties or derive factors that account for those uncertainties.

- Dr. Heinz agreed that lethality and reproductive effects are the two primary endpoints to be concerned with. He was confident that observations in the laboratory correspond to field responses. He repeated his suggestion that EPA try to learn from the past.

- Dr. Rhomberg recommended that the work groups look for general trends in the data, use reasonable generalizations in the absence of empirical data to account for unknown factors, and reevaluate the trends periodically to make sure they fit with current knowledge.

ATTACHMENT A

Agenda, Speaker List

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

UNCERTAINTY ISSUES IN HAZARD ASSESSMENT

Washington Information Center
401 M Street, SW
Washington, DC 20460
April 30, 1990

Agenda

9:00am	Opening Remarks - Steve Bradbury, Environmental Research Laboratory, Duluth
9:15am	Endpoint and Time Period Extrapolations in Aquatic Systems - Foster Mayer, Environmental Research Laboratory, Gulf Breeze
9:45am	Discussion
10:00am	Species Extrapolations in Aquatic Systems - Glenn Suter, Oak Ridge National Laboratory
10:30am	Discussion
10:45am	Break
11:00am	Toxicity Bioassays and Extrapolation Issues - Ron Preston, Office of Emergency and Remedial Response
11:15am	Discussion
11:30am	Open Discussion - Extrapolation Methods in Aquatic Systems
12:00pm	Lunch
1:00pm	Avian Issues - Gary Heinz, U.S. Fish and Wildlife Service
1:30pm	Discussion
1:45pm	Mammalian Issues - Lorenz Rhomberg, Office of Research and Development
2:15pm	Discussion
2:30pm	Open Discussion - Methods for Extrapolation in Terrestrial Systems
3:30pm	Summary and Wrap Up - Steve Bradbury, Environmental Research Laboratory, Duluth

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

UNCERTAINTY ISSUES IN HAZARD ASSESSMENT

Speakers

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APPENDIX C

U.S. ENVIRONMENTAL PROTECTION AGENCY
Risk Assessment Forum Colloquium Series on Ecological Risk Assessment

Uncertainty Issues in Exposure Assessment

May 21, 1990

Introduction

This report summarizes the discussion at the third colloquium, held May 21, 1990, in Washington, DC, in the Washington Information Center, 401 M Street, SW. The discussion focused on identifying the characteristics of the biotic and abiotic environment that may be important to an ecological exposure assessment. To that end, the group discussed how activity and/or growth patterns influence exposure routes and extent of exposure; problems with laboratory-to-field extrapolations; sources of uncertainty; and the recovery potential for impacted systems.

Attachment A to this appendix contains the agenda and list of speakers; references and handouts supplied by the speakers are listed in Appendix H. Dr. Larry Burns, of EPA's Environmental Research Laboratory in Athens, Georgia (ERL-Athens) chaired the meeting. Several invited participants presented issues concerning the assessment of environmental exposure for avian, terrestrial and aquatic species. These speakers were:

Avian Wildlife
- Louis Best, Iowa State University
- Crystal Driver, Battelle Northwest

Terrestrial Systems
- Bill Lower, University of Missouri

Aquatic Systems
- Frieda Taub, National Research Council and ERL-Athens
- David Yount, ERL-Duluth
- Donald Mount, ERL-Duluth
- Michael Mac, U.S. Fish and Wildlife Service

Sue Norton, of the Risk Assessment Forum, explained that EPA Risk Assessment Guidelines are meant as internal documents that provide EPA risk assessors with information on the Agency's position on current issues in risk assessment, as well as new research and procedures that may prove helpful in performing risk assessments. They are not "rulebooks, cookbooks, or textbooks," although these guidelines will need to supply more basic information than the current EPA health risk assessment guidelines because of a general lack of knowledge about ecological systems.

The Ecological Risk Assessment Guidelines are in the very early stages of development, and these colloquia will provide the Guidelines Work Groups with information on how ecological risk assessment should be carried out. At this meeting, the participants discussed several issues in detail, addressing both terrestrial and aquatic systems:

- Defining exposure.
- Routes of exposure.
- Determining the extent of exposure.
- Methods for assessing exposure.
- Indicators of exposure.
- Uncertainties and considerations in exposure assessment.
- Multiple exposures - recovery of ecological systems.
- Controlling exposure.

Defining Exposure

Dr. Burns provided a definition of exposure: contact between living things and things that can cause them harm.

Dr. Taub also listed proposed definitions of exposure for aquatic systems, and the considerations associated with using them:

- The concentration of material in water, sediment, or food. This definition works well, because analytical methods exist that can be used to quantify the exposure.
- The concentration of material in the water, sediment, or food, and the amount of time the organism comes in contact with it. This definition has some merit, because animals are not necessarily exposed to all of the compound present.
- The concentration of the material that is available to the organism. Using this definition would require more research to determine which organisms are exposed, and under what conditions?
- The total concentration of the material present, and the factors that affect bioavailability. This requires more research into the factors that determine bioavailability, as well as a model that can incorporate all of the available data.

Dr. Taub advised the Guidelines Work Groups that exposure data will be submitted according to any one of these definitions, and the risk assessor should have guidance regarding how to work with whatever is supplied, or when to require additional data.

One participant asked if the first definition, which defines exposure by the chemical's presence alone, would be the easiest to use in the Guidelines. Dr. Taub cautioned that some will not be satisfied with that definition for the Guidelines. It can be argued that the material is only present, not necessarily available to the organisms. Others thought that information on the actual dose, not only on potential exposure, is needed to assess effects on organisms. The amount of material present can be relied upon to characterize the contamination of the ecosystem, however, and may be considered an indicator of the maximum potential exposure.

Routes of Exposure

Avian Species

Drs. Best and Driver explained that avian populations can be exposed to chemicals via ingestion, dermal absorption, and inhalation, with ingestion usually the most important. Exposure via ingestion can be due to contaminated seeds, treated vegetation, dead or dying insects or animals killed by pesticides, pesticide granules (grit-ingesting birds are especially susceptible, and adherent granules may contaminate worms or other food), contaminated water, contaminated feathers (in which compounds are incidentally ingested during preening), and other treated media (for example, contaminated soil may be a source of exposure to soil-probing birds or during dusting). Dr. Driver explained that feeding and incubation studies provide information on these routes of exposure, but her tests using a simulated field of cotton row crops in a wind tunnel have shown that, while feeding is an important ingestion pathway, it is not the most important. Preening is the most important source of ingestion exposure, especially by birds that are present during spraying.

Dermal exposure is the next most important route of exposure for avian wildlife. Birds in wet environments are especially susceptible to compounds absorbed from contaminated water. Eggs and young in the nest, as well as the incubating bird, can be exposed to contaminants in the nesting materials, and young can be contaminated by chemicals on the nurturing parent. Finally, birds may take dust baths in contaminated soil. Dr. Driver stated that feather shafts are excellent conduits for contaminants to the birds' skin. Contaminants are also absorbed through the feet and commonly through the eyes.

Inhalation exposure is the least important route overall for avian exposure to contaminants, although Dr. Driver has found that during the first hour after spraying, it is the most important. Volatilization of chemicals in the nest is the most likely inhalation exposure pathway for young birds or incubating adults.

Dr. Driver pointed out that the dermal and inhalation routes of exposure bypass metabolism in the liver, which may potentiate or degrade the contaminant's toxicity.

Aquatic Species

Aquatic species are exposed to contaminants via ingestion, dermal exposure, and respiration. Some benthic and epibenthic invertebrates ingest sediment, as do some deposit-feeding fish. Suspended particles can also be ingested. Egg exposure via the parent fish is also possible, especially in older fish that have been exposed for a long time.

Determining the Extent of Exposure

Avian Species

Many of the chemical and physical properties of the compound and habitat influence how and whether the organism will be exposed to the contaminant. Dr. Best listed some of the parameters that influence the duration and extent of exposure, including:

- The chemicals' and their metabolites' persistence in the environment.
- Duration, frequency, and area of application.
- Time of application, which determines whether migratory or resident, territorial or nonterritorial birds will be exposed, and which lifestage may be affected.
- The birds' diet, which may change with the season, availability, or lifestage.
- The birds' feeding habits and feeding substrate - whether they poke into the ground, eat seeds from the soil surface, or glean foliage.
- The birds' trophic position, which determines the amount of exposure due to bioaccumulation in raptors.
- Whether the bird is restricted by nestlings to a limited feeding zone, or is free-ranging.

- Body size, which affects how the contaminant is metabolized.
- The food/biomass ratio, which determines dose.
- Whether the contaminant is available to the bird. For example, some pesticide granules are highly visible to birds and are available for eating. Also, poisoned insects sometimes act irregularly, making them more visible to the bird, and therefore more likely to be eaten. Research has been performed to assess birds' grit-use patterns and evaluate the characteristics of the grit that birds choose (e.g., color, size). The researchers hope that, by characterizing what type of grit birds prefer, they can encourage pesticides manufacturers to produce granules no bird would accept.

Habitat characteristics, such as the type of edge, type of crop, and land management practices also affect how and whether the birds use an area. EPA-funded studies have determined that birds use fields more if crop residue is not plowed under (as in no-till agriculture). Dr. Best has conducted research to determine how the agricultural landscape influences avian use of the area. He explained that the species most affected by pesticides on treated fields are birds that live and feed in the edge habitat, who often foray into the treated fields during feeding. Also, population levels are higher in the edges. By studying land-use patterns over matrices of numerous fields and other surrounding habitats, he has found that areas with stream interspersion are more attractive to bird species. Water pooled on the field will also attract birds to feed and nest. This type of research is especially useful for assessing larger birds' exposure. The birds' whole territory is monitored, providing information about influencing factors far from the contaminant source.

Dr. Driver explained that the uptake of pesticides, especially via the dermal route, depends on the birds' habits and the conditions in the field. For example, perching birds absorb sprayed pesticides through their feet. Impacts of aerial application of pesticides varies with the humidity and temperature - not so much due to changed breathing rate in the bird as to different partitioning of the chemical in the environment. Humidity and temperature affect the droplet size and volatilization characteristics of the spray.

Aquatic Systems

Currently, exposure models are good for nonpolar, nonmetallic, moderately hydrophobic compounds; however, more research and better models are needed to predict availability to polar, hydrophobic compounds. Dr. Taub explained that determining dose, more than exposure, is important to evaluating an effect on an organism. Bioavailability is determined by uptake and excretion by the organism, as well as the equilibrium concentrations in the surrounding system.

Dr. Mac detailed the three characteristics that affect bioavailability from sediments:

- Sediment characteristics.
- Chemical characteristics.
- Organism behavior.

Sediment Characteristics. Particle size, clay type, and pH are three characteristics that influence the binding capacity of the sediment, and therefore the availability of the compound to the water column and surrounding organisms. Organic carbon present in the sediment binds much of the contaminant in the sediment, but it also serves as food for bottom feeders, and is a source of exposure. In fact, if the contaminant concentration in the sediment is normalized with the concentration of organic carbon, a dose-response curve for the sediment can be determined.

Most laboratory experiments that estimate the amount of contaminant binding to organic carbon in sediment use radiolabeled compounds. These radiolabeled compounds have a different binding affinity with the sediment than do unlabeled compounds. Also, the natural binding characteristics of sediment used in these tests often changes with handling.

An attendee asked if any perturbation studies have been conducted with contaminated sediments to determine the strength of binding and the availability from suspended particles.

Dr. Mac explained that mechanical resuspension studies have not worked very well to date, but some bioperturbation studies may prove informative in that area.

Another attendee pointed out that water quality criteria are being considered for regulating discharges to wetlands, because of the large amount of organic carbon that is available to bind contaminants and keep them out of the water column. This may not be reasonable, especially if fish and invertebrates use that organic carbon for food?

Finally, sediment sulfides (called acid volatile sulfides, or AVS), which compete for free metals in the sediment, may be present at different concentrations. The concentration of AVS may determine the concentration of the free metals in the overlying water. To a question concerning the variability of AVS concentration in the sediments, Dr. Mac explained that methods for measuring that variable are still in developmental stages. Most work to date in that area has been performed in the laboratory.

A participant asked if the reduction-oxidation potential for sediments has been used as a characteristic measure. Most sediments are reducing agents, Dr. Mac replied, but redox potential is an important consideration, that characteristic of the sediment may alter the contaminant. Eutrophication of the sediments is another consideration, he continued, but most sediments studied are extremely contaminated and primarily anaerobic.

Chemical Characteristics. The octanol/water partitioning coefficient (logP, or k_{ow}) for a chemical indicates whether the compound will be in the water or sediment phase. If logP is greater than 7.0 or 7.5, then the compound will bind tightly to the sediments. If logP is less than 3.5 to 4.0, then it will dissolve in the water. It is more difficult to predict the binding of chemicals with logP between 4.0 and 7.0; many persistent chemicals of environmental concern (e.g., PCBs) fall in this range.

An extension of logP is the Equilibrium Partitioning (EP) Approach, which assumes that at equilibrium:

$$\frac{[x]_{sed}}{\%\ \mathrm{OC}} = \mathrm{logP}\ \mathrm{x}\ [x]_{dis}$$

where:

$[x]_{sed}$ = concentration of contaminant *x* in the sediment.
% OC = percent organic carbon in the sediment.
$[x]_{dis}$ = concentration of *x* dissolved in the water column.

If the equation is solved for dissolved concentration, then water quality criteria can be used to set sediment concentration limits for the compound. This approach, however, does not account for exposure via ingestion. Deposit feeders eat settled organic carbon, and digest 30 percent of the amount ingested. A researcher at the National Oceanic and Atmospheric Administration has found that the relative contribution to exposure from food varies with the chemical, but is not related to logP.

How and whether the compound is metabolized also affects the amount of toxicity the to which the organism will be exposed.

Organism behavior. Invertebrates and fish are exposed to contaminated sediments, because they are sediment or deposit feeders, bottom feeders, or filter feeders. To make the assessment more difficult, some fish are only occasional bottom feeders. There are several good bioaccumulation models available, stated Dr. Mac; however, some assume that the fish lipid and sediment concentrations equilibrate. Research has shown that this relationship does not reach steady-state; instead, lipid concentrations increase with age, sometimes surpassing the sediment concentration. Dr. Taub added that sediment concentrations are not always the same from one site to the next, and fish may be exposed to varying concentrations of contaminant. Models that are based on energetics appear more useful.

A Guidelines author asked the speakers to rank the parameters that had been discussed according to importance in an exposure assessment. The speakers agreed that the most sensitive parameters are not yet determined for terrestrial or aquatic systems, but that the process of devising models will help determine which are most important. They also agreed that terrestrial data are too sketchy to allow modeling at this point. The speakers stated that there are several areas in which data are missing from the terrestrial data base as it is now. These include occurrence data for environmental chemicals and their concentrations, and animal usage patterns.

Methods for Assessing Exposure

The speakers discussed the ways in which researchers assess exposure in terrestrial and aquatic systems. They explained that most research is performed in the field - few were confident that laboratory testing alone would provide sufficient data for risk assessment.

Terrestrial Systems

Field vs. Laboratory Studies. Dr. Best explained that currently most avian field studies assess mortality due to contamination. These studies are performed by marking birds before application and collecting dead or dying birds after spraying; counting dead and dying birds in control and treated fields; or attaching radiotransmitters to larger birds to trace their movement before, during, and after spraying. Laboratory and pen studies are used to assess motor impairment, but he cautioned against using these types of studies for extrapolation to potential effects in the field. He thought that laboratory studies are more suited to refining information gathered in field studies. For example, birds introduced into pens after treatment seldom eat for the first 24 hours. This behavior significantly affects exposure patterns. Too many variables come into play in the field that cannot be accounted for in the laboratory, and the interactions present in the field are ignored in laboratory studies. Nest boxes, an alternate to pen studies, in which birds are observed via monitors, are used to assess changes in feeding or behavior. Dr. Driver is concerned about these types of studies, however, because the resins used in most boxes themselves induce enzyme activity, complicating the assessment.

Field studies that maximize risk from chemicals should not be used to assess exposure, Dr. Best warned. Such studies do not give a realistic overview of the species present, and cannot characterize the interactions in a natural system. When asked, Dr. Best explained that these assays will not always overestimate results, but always oversimplify the system. A participant asked whether that degree of simplification is acceptable for Guidelines, if the Work Group members want to take a more conservative stand. Dr. Best said that the Guidelines could propose these types of studies, but stressed that the Guidelines should also detail the uncertainties state that such studies produce a worst-case estimate. For example, in a sink population, data on species abundance can be misleading - the numbers of birds may seem high, but the actual productivity of the population may be low.

Dr. Driver expressed dissatisfaction with feeding studies, which often produce anorexia in the test birds. This condition has never been observed in the field, she stressed, indicating that feeding studies are not adequate substitutes for field studies. Her field simulation studies have been successful in assessing exposure to birds during and after aerial pesticides spraying, because the use of a large artificial habitat for the test birds helps to assess exposure by all routes, but is also controlled enough to produce reliable results.

A participant asked what proportion of migratory birds' exposure comes from outside United States' jurisdiction. To date, few baseline data have been gathered, and since previous exposure could potentiate effects observed during nesting, residual contamination could be a major source of body burden of certain pesticides. Research in this area may be necessary.

A participant asked how the Guidelines Work Groups should deal with the lack of assessment methods for avian species, and deciding which species to use. Dr. Driver suggested that non-native species could be used on site. For example, homing pigeons have been trained to stay in a localized area, and used as sentinel species. Dr. Best suggested that the risk assessor perform two exposure assessments, one for migrating birds and one for resident species. for migratory birds, however, sequential exposure over time and space becomes very important.

Sentinel Species. Dr. Lower proposed the use of sentinel or surrogate species to assess ecological exposure. A sentinel species is:

> any domestic or wild microorganism, plant, or animal that can be used as an indicator of exposure to and toxicity of a xenobiotic, that can be used in the assessment of the impact on human and/or environmental health because of the organism's sensitivity, position in a community, likelihood of exposure, and geographic and ecological distribution or abundance...

He suggested that, rather than studying perturbations' effects on organisms in the field, researchers should use sentinel organisms to identify perturbations in the field. The sentinel approach combines field observations with laboratory bioassays to determine contaminant concentrations in tissues, and to measure the occurrence of DNA, RNA, and protein adducts in fish, birds, and plants. Dr. Lower provided a list of possible sentinel species (Attachment C), all of which are common species widely distributed across the United States. He suggested that any species can be a sentinel species for a certain impact; the researcher should make a list of the characteristics he or she needs in a test species, then ask an expert for suggestions. For example, Dr. Lower's laboratory has chosen to work with the spiderwort, *Tradescantia*, for several reasons. In addition to being easy to take care of, it can be used:

- In the lab or field.
- For chronic (month-long) or acute (several minutes-long) tests.
- To assess air, water, and/or soil contamination.
- As a whole organism or in parts.
- To assess numerous endpoints, including germinal or somatic cell development; several aspects of photosynthesis; growth; pollen perturbation; pollen abortion; and DNA adduct formation.

Dr. Lower demonstrated that sentinel species and toxicity tests can be used to assess contamination over space or time, or both, with two case studies. The first measured mutation frequencies in corn and *Tradescantia* at various distances from a lead smelter; the second measured TCDD concentration in several species over time and distance from a contaminated roadside at Times Beach, Missouri (a Superfund site).

Dr. Taub asked if the choice of a sentinel species should take social considerations into account. Dr. Lower pointed out that all research proposals are influenced by "social importance" - that is, a deer is more valued than a mouse by the population at large. Social relevance could be included as a criterion for choosing the sentinel organism. Another participant stressed that regulators must set standards that will encourage testing of the most scientifically significant organisms, not the "cute and fuzzy" ones. The guidelines should support the choice of the most sensitive organism. One participant suggested that perhaps the risk assessment should use effects on processes as endpoints, rather than effects on certain species. For example, a level of contamination would be considered unacceptable when photosynthesis is inhibited (which Dr. Lower considers the most important ecological endpoint). Several present agreed with this method of regulating exposure. Dr. Taub added that not only acute effects, but chronic effects should be assessed.

Aquatic

Laboratory and field testing for aquatic systems is far ahead of testing in terrestrial systems, participants agreed. Pen studies in the field, laboratory toxicity tests measurements of sediment concentrations, and mesocosm studies all contribute to the exposure data base for aquatic species. Dr. Taub explained that most aquatic data are based on ambient concentrations in the sediment or water. She suggested that measured organism internal doses may not provide a good assessment, either, because the chemical may have been metabolized or excreted, and therefore be unidentifiable. She suggested some parameters that may provide better indications of exposure: uptake, or uptake over time; average body concentrations; blood concentration (before or after liver or kidney passage); or target organ concentration.

She added that it would be useful to conduct a survey of the mesocosm studies that are available, to determine what kinds of useful information can be gleaned from them.

Indicators of Exposure

The speakers listed effects, not necessarily adverse in themselves, that indicate exposure in laboratory or field studies.

Avian Wildlife

Dr. Best listed several effects resulting from exposure to toxins:

- Reduced survival.
- Altered behavior that can cause changes in breeding, care of young, inter-species interactions, and food consumption.
- Increased vulnerability to predation.
- Impaired reproduction.
- Changes in physiological condition.
- Decreased nestling growth or shortened breeding season due to decreased food supply.
- Decreased resistance to disease and weather.
- Loss of habitat due to herbicides.

A participant asked if altered behavior is a reliable endpoint, and whether it is an effect or indicator of exposure. Dr. Driver said that behavioral measurements are difficult to quantify, but can be indicators of exposure; for example, abandonment of the nest can indicate hormonal changes. Dr. Burns suggested that an avoidance behavior indicates both effect and exposure. One participant added that behavioral measures may be useful for predicting the location of birds during spraying, and thus the extent of exposure. Dr. Best explained that behavior is difficult to assess in the field, and as a result, researchers probably do not have a good idea of its importance.

Aquatic Species

Dr. Mac listed some endpoints that indicate exposure, such as fin rot, stubbed barbel, and effects on fish embryos as a result of maternal exposure during egg production.

Uncertainties and Considerations in Exposure Assessment

The speakers outlined some of the uncertainties involved in assessing exposure, and some considerations that must be taken into account when estimating exposure based on testing data.

Avian

- Most avian assessments are based on acute effects, e.g., mortality.
- Effects that are delayed in space and time are difficult to assess; therefore, it is easier to assess onsite impact than potential impacts off site.
- Exposure during migration should be assessed.
- Even resident species still move outside their home zone for breeding and wintering, which makes it difficult to assess exposure from a single area.
- Mortality studies tend to be biased toward healthier animals, because they are more easily found. It is also difficult to know how many birds die outside the area. Finally, humans may impact the results by disturbing the natural course of events in the field.
- Perceptions of taste, smell, and sight differ between birds and humans, and even among bird species. This must be considered when developing testing protocols.
- Assays used for agroecosystems and certain species are probably applicable to other situations, such as wetlands or hazardous waste sites.

Aquatic

- Sediments are not homogeneous, and fish migrate in and out of feeding areas, so fish should not be assumed to be in equilibrium with the surrounding sediment or the water in the immediate vicinity.
- Concentrations of contaminants in the water column can vary vertically.
- Organisms themselves change abundance and distribution within the water body, and are not evenly distributed vertically.
- Organisms change their diet seasonally, with changes in lifestage and food availability.
- Predatory fish feed on different organisms, depending on other predators present.
- Organisms that seem more resistant may have been genetically selected to survive that particular stress.
- Changes in water chemistry alter biological activity, and vice versa. For example, fish will avoid areas in a lake where there are decreased levels of dissolved oxygen. Or an algal bloom will cause higher pH.
- Chemical degradation and chemical interactions are more likely to occur in complex ecosystems than in test systems.
- Indirect ecological effects are likely to differ seasonally.
- Organisms in natural systems are neither subject to changes in temperature, diet, etc., unlike test organisms, nor must they compete for food or avoid predators.
- Ecosystem processes may mask effects.
- Effects may modify exposure.

Any change in any part of the system eventually impacts the entire system. Dr. Taub presented a chart showing the abiotic and biotic interactions involved in a lake ecosystem, demonstrating that all parts are interdependent. She stressed that these interactions are not easily predicted using population models; instead, ecosystem models must be used. A participant asked if biotic factors are as important in streams as they seem to be in lakes, suggesting that abiotic factors would seem to be more important in a smaller water body. Dr.

Taub thought that biotic factors would be more difficult to assess in a stream or river, because of greater movement and constant change.

Multiple Exposures - Recovery of Ecological Systems

Dr. Yount described a means for assessing the ability of an aquatic system to recover from exposure. First, he provided three definitions of disturbance:

- A relatively discrete event that disrupts ecosystem, population, or community structure; a change in resources or available substrate.
- Discrete or punctuated killing or displacing of one or more individuals, opening an opportunity for other organisms.
- An out-of-the-ordinary occurrence - annual flooding is not a disturbance.

A pulse disturbance is generally localized, and lasts for less than one generation; recovery is due to other organisms moving into the area from unaffected areas. A press disturbance deforms the system over a long period; the system responds by genetic selection and slowly recovers. Recovery is defined as:

- A return to conditions that existed before the disturbance.
- Achievement of a stable condition.
- A return to normal bounds within which the system can subsist.
- A return to a condition that resembles surrounding unstressed areas.

Dr. Yount used these definitions to survey more than 150 case studies in which recovery was reported. His group studied each case and assessed the recovery of the system by reviewing the endpoints observed and the length of time recorded. Most of the endpoints that signaled recovery were structural in nature: recovery to an average size, previous density, or total biomass, or the first reappearance of a previously affected species.

The researchers found that several factors affect recovery rate, including:

- Characteristics of the system or community, such as productive capacity, biomass turnover rate, flushing rate, food web structure, presence of refugia (areas for the organisms to "hide" during the disturbance).
- The disturbance regime determines what effect the disturbance will have on the system. Factors such as generation time, organisms' behavior, the chemicals' dispersal characteristics, and the organisms' lifestage.

These factors determine whether the system will recover immediately from a sharp decline, or will gradually degrade, without sign of recovery.

Few of the case studies used actually assessed recovery, so the results were studied to find clues as to preexposure conditions, and any endpoints that indicate recovery. The conclusions included:

- Macroinvertebrates recovered more quickly than fish.
- Small fish species tend to recover faster than larger fish due to their increased dispersion and shorter life cycles.
- Density, biomass, and richness usually demonstrate a 90 percent recovery in 0.75 to 1 year.
- Communities pulse-exposed to chemicals recover faster (in 1 to 2 years), while physical disturbances, such as channelization, require the longest recovery times (10 to 20 years). Most recoveries occurred in 1 to 3 years.
- There is limited evidence that functional feeding group structure may not recover as quickly as taxonomic richness.
- Refugia are extremely important to the recovery of the system.
- Communities recover faster from anthropogenic disturbances that mimic natural disturbances.

Dr. Yount explained that the data from this survey are biased by an emphasis on smaller streams, especially in the data that focus on particular taxonomic groups, species richness, or biomass as recovery endpoints. He suggested that his group had taken all the information possible from the existing data base, and proposed that future studies should consider:

- Long-term research and monitoring, especially in large rivers.
- The influence of ecosystem processes on recovery.
- The influence of scale on the biological characteristics of habitats.
- The influence of interactions between an organism's life history and the disturbance regime.
- The influence of recolonization processes on the community's ability to recover.
- The best management practices to ameliorate or mitigate the effects of disturbances.

Discussion

The group discussed the frequency of exposures and effects on recovery. Dr. Yount stated that as long as an anthropogenic disturbance is not more frequent than a natural disturbance, the system will probably recover acceptably. Some participants disagreed because background stresses may be additive or synergistic with the applied stress; or the community could recover without individual species recovering. Dr. Best suggested that the recovery depends on how open or localized the system is, and whether there are others of the same species to recolonize. When asked, Dr. Yount explained that the functional parameters of a community will recover faster than the structural components of the community, and that the underlying structure must return for the community to recover fully.

Finally, Dr. Yount presented the table of contents and preface to a symposium to discuss "Recovery of Lotic Communities and Ecosystems Following Disturbance: Theory and Application" (available from EPA; see Appendix H). In the symposium proceedings document, the speakers discuss several recovery theories - the secondary succession theory; the island biogeographic theory; and natural selection.

Controlling Exposure

Dr. Yount explained how averaging periods are used in the Office of Water's National Pollutant Discharge Elimination System (NPDES) permits and Water Quality Criteria to control aquatic systems' exposure to multiple chemicals. These permits deal with whole, mixed effluents regulated by the Office of Water, and do not apply to accidental spills or Office of Toxic Substances or Office of Pesticides Programs permits.

NPDES permit limits and Water Quality Criteria are based on Criteria Maximum Concentrations (CMC) or Criteria Continuous Concentrations (CCC). These average concentrations limits can be exceeded at any one point in time, but the average over the specified time period cannot be exceeded. The CMC limits the discharge to a specific concentration, averaged over 1 hour, to prevent acute toxicity, and to satisfy the EPA policy of no mortality in the mixing zone. The CCC is an average over 4 days. Previously, the CCC regulated a month's average discharge, but EPA found that lethality was occurring at 5 days in some cases for species with short life cycles, and so chose to limit the number of days that the discharge concentrations could exceed the CCC. Although small fish generally recover faster from exposure than large fish, the Agency decided that a shorter averaging time would protect larger, longer-lived fish and sensitive lifestages. One reason for the discrepancy in recovery rates between small and large fish, Dr. Mount explained, is that the acute-to-chronic ratio for smaller species is almost 1 - that is, the LC_{50} and NOEC are almost equal. Also, one short exposure during a critical stage, such as reproduction or larval development, could affect the population.

Several states use a 7Q10 average for regulating discharges to low-flow streams and rivers. This is the effluent flow that is expected for 7 consecutive days once every 10 years. He suggested that the structure of this averaging period is such that several margins of safety are built into the calculation. The exposure is once every 10 years; the limit is set based on sensitive life stages; the calculation assumes low dilution because of the low-flow characteristics of the water body; and the mixing zones are assumed to be small.

Discussion

Dr. Taub expressed concern that the water quality limits are based only on growth, lethality, and reproduction, whereas many chemicals may be carcinogens. Dr. Mount stated that ecological risk assessment is based on a different set of values than human risk assessment. In humans, one individual with cancer is important for an assessment, but animals are counted as percentages, not individuals.

Another person asked why water quality criteria are based on individual chemicals, when in fact the interactions may make the effects additive. Dr. Mount replied that the current thinking is that chemicals in mixtures are not significantly additive. He suggested that at this point, toxics are not the current problem (because of the strict controls), and stated that sediment contamination, suspended solids, and spills deserve more attention. He added that the majority of areas contaminated sediment may be the result of past contamination, before discharge limits were in place.

Final Notes

The speakers answered the question, "what is the most important variable that should be included in the exposure assessment portion of the Guidelines?"

Dr. Best: habitat use patterns and feeding behavior patterns. He stressed that the Guidelines should be flexible, and able to be adapted to specific sites.

Dr. Driver: routes of exposure and their relative significance, as well as how the species of interest interacts with its environment and its behavior.

Dr. Lower: the species of interest's feeding habits, place in the food web, and mobility in its environment (i.e., birds preen, snakes don't - these factors must be considered).

Dr. Taub: the chemicals' presence in the environment; factors that affect bioavailability and the organisms that may be exposed, and how that changes seasonally; toxicity as it can be measured in the laboratory.

Dr. Yount: how organisms avoid exposure. Also, the Guidelines should ask risk assessors to relate toxicant exposure and effects to naturally occurring disturbances in the system to make sure there is no cumulative effect.

Dr. Mac: the chemicals' effects on organisms high in the food chain.

Dr. Burns: risk assessors must understand the ecological relationships among the species.

ATTACHMENT A

Agenda, Speaker List

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

UNCERTAINTIES IN EXPOSURE ASSESSMENT

Washington Information Center
401 M Street, SW
Washington, DC 20460

May 21, 1990

Agenda

9:00am	Opening Comments - Larry Burns, Environmental Research Laboratory, Athens
9:15am	Exposure of Avian Wildlife I - Louis Best, Iowa State University
9:45am	Exposure of Avian Wildlife II - Crystal Driver, Batelle Northwest
10:15am	Discussion
10:45am	Break
11:00am	Exposure and Terrestrial Sentinel Organisms - Bill Lower, University of Missouri
11:30am	Discussion
12:00pm	Lunch
1:00pm	Methods and Uncertainties in Estimating Aquatic Exposure - Frieda Taub, Environmental Research Laboratory, Athens
1:30pm	Discussion
1:45pm	Pulse Exposures and Recovery of Aquatic Communities - David Yount, Environmental Research Laboratory, Duluth
2:15pm	Discussion
2:30pm	Break

May 21, 1990 Agenda, cont.

2:45pm	Averaging Times in Aquatic Systems - Donald Mount, Environmental Research Laboratory, Duluth
3:15pm	Discussion
3:30pm	Exposure to Contaminated Sediments - Michael Mac, U.S. Fish and Wildlife Service
4:30pm	Discussion
4:45pm	Closing Comments - Larry Burns, Environmental Research Laboratory, Athens

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

UNCERTAINTIES IN EXPOSURE ASSESSMENT

Speakers

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APPENDIX D

U.S. ENVIRONMENTAL PROTECTION AGENCY
Risk Assessment Forum Colloquium Series on Ecological Risk Assessment

Population Modeling

July 9, 1990

Introduction

This report summarizes the discussion at the colloquium held July 9, 1990, in Washington, DC, in the Washington Information Center, 401 M Street, SW. The invited participants described existing methods for modeling population response to stress and discussed the role of those models in characterizing ecological risk. The group also discussed whether and how population modeling may be incorporated into the Ecological Risk Assessment Guidelines and the regulatory process. The Guidelines Work Group asked the speakers to address several issues, including:

- What criteria should be used for selecting "assessment and measurement" endpoints at the population level?
- What types of models are available, and what are the critical assumptions, limitations, data requirements of each?
- What criteria can be used to determine "biological or ecological" significance of population changes?

Dr. David Mauriello, from EPA's Office of Toxic Substances, chaired the meeting.

Attachment A to this summary includes the agenda and list of speakers; references and handouts supplied by the speakers are listed in Appendix H.

Using Matrix Population Models for Ecological Risk Assessment

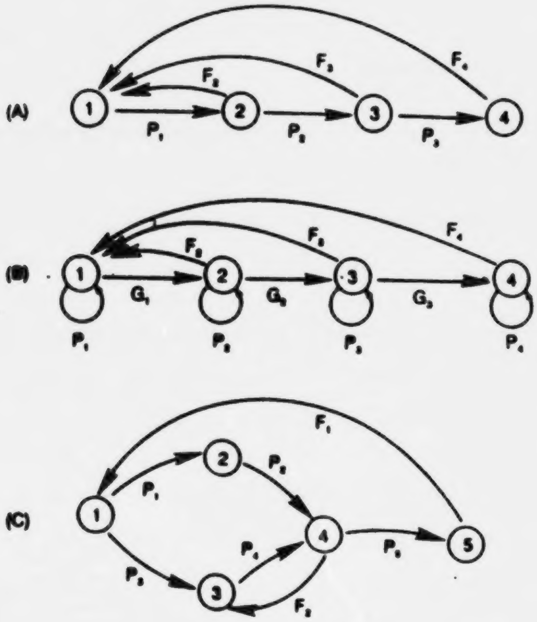
James Weinberg, Woods Hole Oceanographic Institution

Dr. Weinberg discussed the uses and applications of perturbation (or sensitivity) analysis in ecological risk assessment. *Perturbation* is a change in the life cycle (or life table) of an organism due to chemical, biological, or abiotic causes, whether naturally occurring or caused by humans. Dr. Weinberg described matrix population modeling as a way to rank the relative importance of perturbations on the individual organism's life cycle, and determine the resulting effects on the population as a whole.

Matrix Theory

Matrix modeling involves "decomposing" the life cycle of an organism into its component parts, or measurable quantities. The process begins with a schematic drawing of the life cycle with each life stage represented (see Figure D-1), then applies coefficients for the vital rates between the stage classes: P is the probability of survival from one stage to the next; F represents fertility. Arrows imply impact of one stage on the next over one unit of time. The simplest form of life cycle is called an age-classified life cycle (A), (B) is a size-classified life cycle in which individuals can grow no more than a single size class over one time interval, and (C) illustrates a hypothetical life cycle where both sexual and vegetative reproduction takes place. The coefficients are compiled in a mathematical matrix that describes the rate of growth for an individual organism. From this matrix, several properties of the population of individuals with that life cycle can be estimated, for example:

- Population growth rate.
- Stable stage distribution.
- Reproductive value.
- Which portions of the life cycle contribute most to the overall life table, and therefore which vital rates are most important for research.
- Sensitivity to perturbation (sensitivity analysis).


(A)
1
2
3
4
P1
P2
P3
F2
F3
F4
(B)
G1
G2
G3
P1
P2
P3
P4
(C)
5
F1
F2
P1
P2
P3
P4
P5

$$\mathbf{A}_a = \begin{pmatrix} 0 & F_2 & F_3 & F_4 \\ P_1 & 0 & 0 & 0 \\ 0 & P_2 & 0 & 0 \\ 0 & 0 & P_3 & 0 \end{pmatrix}$$

$$\mathbf{A}_b = \begin{pmatrix} P_1 & F_2 & F_3 & F_4 \\ G_1 & P_2 & 0 & 0 \\ 0 & G_2 & P_3 & 0 \\ 0 & 0 & G_3 & P_4 \end{pmatrix}$$

$$\mathbf{A}_c = \begin{pmatrix} 0 & 0 & 0 & 0 & F_1 \\ P_1 & 0 & 0 & 0 & 0 \\ P_3 & 0 & 0 & F_2 & 0 \\ 0 & P_2 & P_4 & 0 & 0 \\ 0 & 0 & 0 & P_5 & 0 \end{pmatrix}$$

Figure D-1. Schematic drawings of three representative life cycles: (A) age-classified life cycle, (B) size-classified life cycle, and (C) a hypothetical life cycle including both vegetative and sexual reproduction.

Sensitivity Analysis

Sensitivity analysis can be used to:

- Measure how important a given vital rate is to population growth.
- Quantify the effects of environmental perturbations.
- Predict the intensity of natural selection.
- Evaluate alternative environmental management strategies, for example, selecting for certain life stages in the system.
- Evaluate the effects of errors produced in estimating vital rates for inclusion in the matrix.

Sensitivity to perturbation has been studied in detail by Hal Caswell (Woods Hole Oceanographic Institution), who has developed a method for determining the relative importance of the coefficients of the life cycle, or a_{ij}s (so named from their position in the matrix) on the population growth rate (λ).

$$\frac{d\,\lambda}{da_{ij}} = v_i w_j$$

Dr. Weinberg provided additional examples of the uses of sensitivity analysis. He has performed research on the interactions between a marine polychaete worm and a bivalve. In a repeated experiment, Dr. Weinberg found that the worm had statistically significant positive effects on the clam in terms of adult growth and survival (first run only) and juvenile growth (first and second runs). The differences between baseline ("normal" population growth) and the same plot when contributions from adult growth and survival and juvenile growth were taken from the equation are illustrated when population size was plotted over time (see Figure D-2). The plot shows that juvenile growth rate has a much greater impact on the overall population growth rate than do adult growth or adult survival.

Another example of the uses of sensitivity analysis is the application of life table response experiments (LTREs). LTREs are experiments in which the matrix, as a collection of

J. R. Weinberg[1,*], H. Caswell[2] and R. B. Whitlatch[1]

Marine Biology 93. 305–310 (1986)

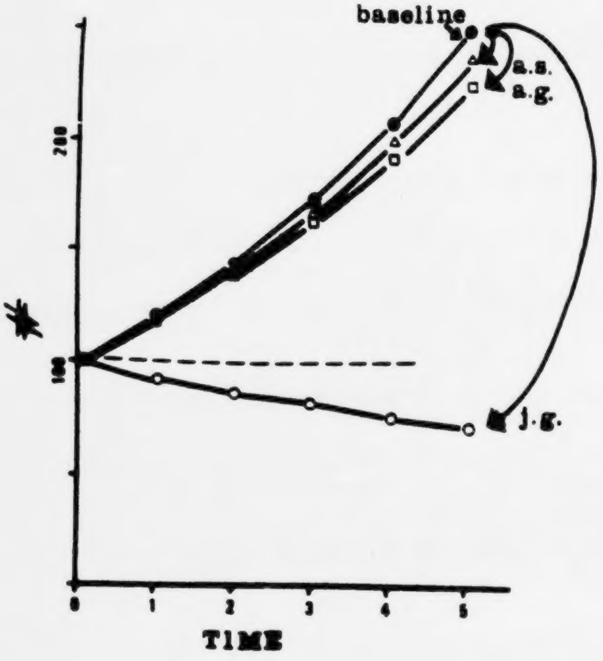


Figure D-2. Trajectories of hypothetical population sizes for *Gemma gemma* when single positive effects of *Clymenella torquata* have been removed. a.s. = adult *G. gemma* survival; a.g. = adult growth; j.g. = juvenile growth.

the vital rates of the organism, is used as the response variable in an experimental design. This method combines analyses of variance and sensitivity. The simplest model uses a one-way ANOVA design to determine how a change in one element of the matrix contributes to the overall treatment effect, weighted by the sensitivity of the overall population growth rate to that element. Levin et al. (*Ecology*, 1987) used this method to compare the relative contributions of effects on fertility and survival during two different life cycles of the polychaete worm *Streblospio benedicti.*

Several assumptions and limitations of the sensitivity analysis approach include:

Assumptions

- Vital rates are age- or stage-dependent.
- Vital rates do not vary in time, space, or with density.
- No migration takes place (or emigration balances immigration).

Limitations

- It is difficult to experimentally measure certain vital rates.
- The model is not realistic enough to predict population fluctuations; however, it is appropriate for population projection and sensitivity analysis. If the goal is to predict populations, then the model can be made more realistic, although it will become more mathematically complex and will be less applicable to a range of situations.

Discussion

Dr. Mauriello stressed two points that Dr. Weinberg raised: first, that the models give projections, rather than predictions, of the population growth. It is important to keep that distinction in mind. Secondly, it is very difficult to measure vital rates, and to obtain accurate measurements, especially from older studies.

A participant stated that other researchers have stated that terrestrial populations are more sensitive to mortality than fecundity. She wondered why Dr. Weinberg's data shows the opposite. The difference lies in how the change is expressed. Fecundity is linear in the models, whereas instantaneous mortality changes exponentially. Differences in life history could also account for a change in sensitivity. Finally, if a compensatory mechanism exists, the impact of a stress could be related to timing - if the stress occurs after the potential for compensation, the impact will be much greater.

Dr. Ginzburg asked if migratory locations could be added to the matrix, if it is a linear parameter, and the resulting effects are small. Dr. Weinberg stated that it probably could be done - and it would not have to be completely linear, as all of the components of the matrix are not linear.

Predicting Population Dynamics from Field Data

Michael Fogarty, National Marine Fisheries Service

Dr. Fogarty described methods for quantifying effects of perturbations from harvesting in marine systems. These methods tend to stress modeling, since fisheries species are not usually used in laboratory studies. He stated that many of the issues encountered in producing the models for harvesting effects are similar to those encountered when assessing effects from other perturbations as well, for example, the stability of the population, its resilience, and its response to the stress. The models he described focus on the very early life stages of the organisms, which are most sensitive to environmental impacts and the overall effects of harvesting. The key characteristic that determines the population response, he explained, is the population's ability to recover.

Central to characterizing the recovery of a system from a disturbance is the determination of the degree to which the perturbation affects the normal rates of transition from one life stage to the next. Several factors affect the resilience and stability of fish populations, for example, anthropogenic changes (fishing and pollution), environmental changes in temperature or salinity, and biotic changes such as predation or lack of prey. Determinants of population variability also include internal population factors, for example, some fish and invertebrate populations tend naturally to crash and then recover, seemingly never reaching a stable equilibrium (see Figure D-3). Trophodynamic variability in prey and predator abundance, and physical and chemical factors such as current or salinity stratification also contribute to variability. These natural fluctuations make it difficult to distinguish variability in recruitment induced by anthropogenic factors. Recruitment is defined in fisheries as the size or age at which the population is vulnerable to exploitation; in more general ecological terms, it refers to the number of organisms surviving to the next life stage. Recruitment is a multidimensional parameter, which incorporates egg production and the mean of all environmental factors, biotic and abiotic. The compensation capability of the population lies in the relationship between recruitment and egg production, or spawning stock size, another early life stage parameter.

Dr. Fogarty presented a graph that demonstrates how environmental factors, when combined with a straight recruitment/spawning stock size graph, can predict the ability of the population to withstand stress in the form of harvesting (mortality) (see Figure D-4). The graph represents the recruitment including environmental factors: the upper curve is the recruitment resulting from a favorable (nearly pristine) environment, while the lower curve represents an unfavorable (relatively degraded) environment. Where the straight lines intersect the curves there is a stable equilibrium for the population. When there is low mortality, two equilibrium points exist for the population, in both the favorable and unfavorable environments. There is only one point for stable equilibrium when there is high mortality, however. The combination of environmental factors and high fishing rates will cause the population to crash.

Only the initial slope of the recruitment curve is needed to predict at what mortality rate the population will crash. Dr. Fogarty used historical data to demonstrate the usefulness of this method by predicting a crash for Georges Bank Haddock when the mortality rate exceeded 0.5 (the initial slope of the recruitment curve).

The ability of the population to compensate for the stress is the most important factor in recruitment rate. There are many potential mechanisms for compensation in the population, for example:

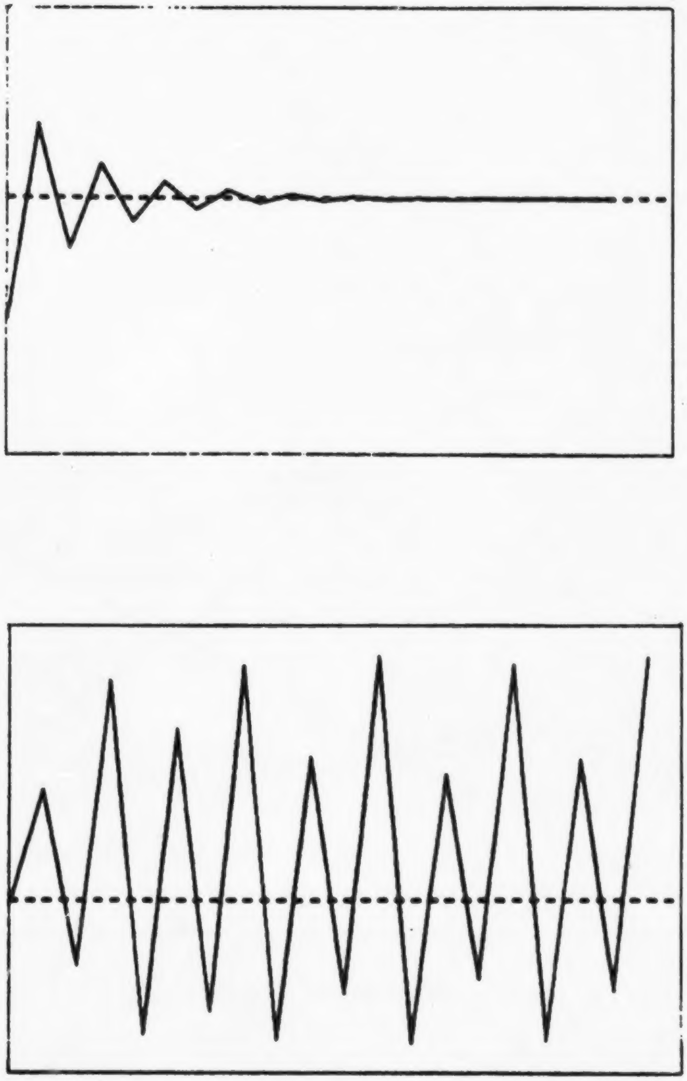


Figure D-3. Abundance vs. time for representative types of populations.

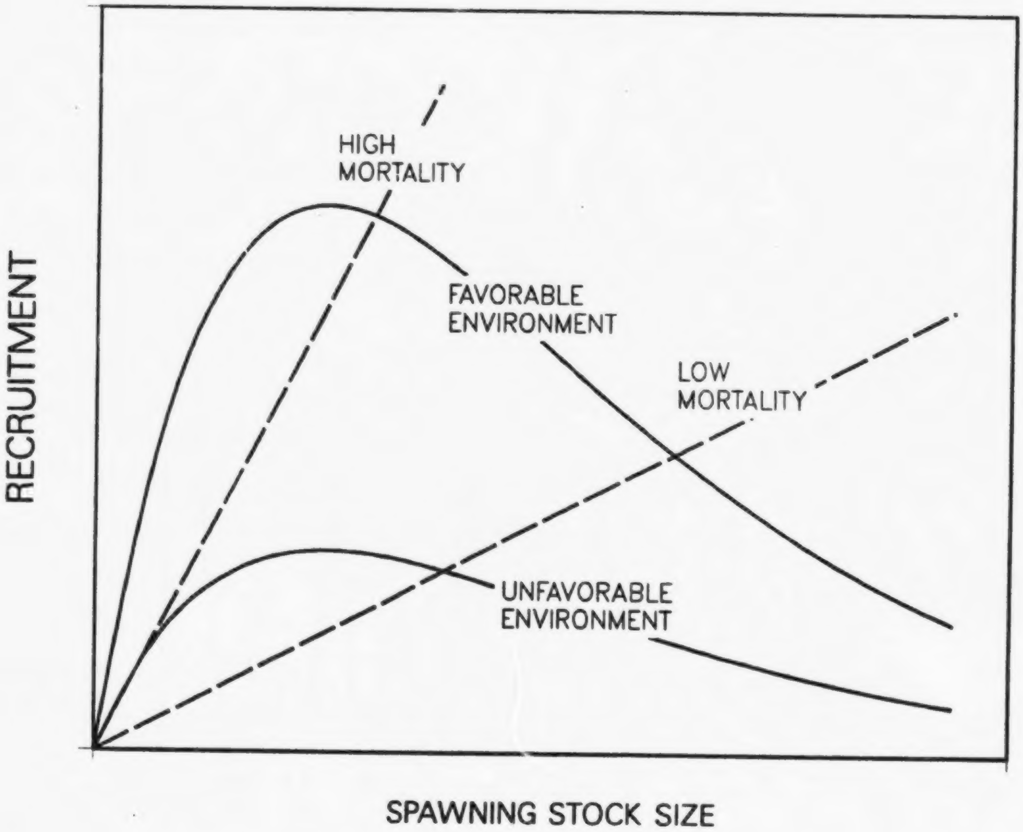


Figure D-4. Recruitment vs. spawning stock size. A stable equilibrium is achieved when the straight lines intercept the curves; a population crash occurs when high mortality coincides with unfavorable environmental conditions.

- Cannibalism.
- Density-dependent growth coupled with the size at which the organism is vulnerable to predation.
- Density-dependent fecundity.
- Intra-cohort competition.
- Density-dependent disease transmission or parasite loading.

If these compensating mechanisms are weak or nonexistent, the recruitment curve would be a neutral (null) model, going straight through the origin, not incorporating any variability at all.

Other models have been developed that characterize the variability in recruitment. The Ricker model relates variance to initial cohort size, taking compensation into account. That model is supported by data that show that the relationship between frequency and adjusted mortality rate is normal, while frequency vs. recruitment is lognormal.

The observed variability in recruitment has many implications for risk assessment, including:

- The existence of a "storage mechanism," in which periodic effect on recruitment keep the species reproducing.
- It helps maintain species diversity.
- It maintains genetic diversity.
- It introduces uncertainty in the form of stock-recruitment relationships.
- It makes setting biological reference points (e.g., fishing mortality rates) difficult.

Forecasting models approach the variability in recruitment in a different way, by relying on information about past population responses to stress to predict future response. Dr. Fogarty called this type of model an autoregressive integrated moving average model, because it combines regression of past data on itself (autoregression) with future random changes in stress and the environment (described in the model's equation as a moving average). Empirical time series and autoregressive integrated moving average models provide a better prediction of recruitment than the normal stock-recruitment model provides (as Figure D-5 shows) because it incorporates much more data.

Other models (transfer-function models) remove the effects of autocorrelation that can produce unreal relationships between input and output from the time series data, in an attempt to identify the key diagnostic characteristics of the autocorrelation. With these types of models, a single discrete impact, for example an oil spill, could act as a variable.

Discussion

One person suggested that these models can be used in the guidelines to address natural variability. Dr. Fogarty stated that the models can be used in conjunction with other models to provide a more complete picture of the factors influencing population response. One participant asked if projection (matrix) models and empirical models could be used to check each other. Dr. Fogarty thought it would be possible. Both types of models could also be used to detect perturbations.

Referring to the graph depicting the Georges Bank haddock decline (Figure D-6), Dr. Weinberg asked what caused the recruitment to increase in 1963. Dr. Fogarty stated that a single factor was not identified as the cause, but that the crash was probably due to a cumulation of factors, including fishing, but also density-dependent factors. Dr. Mauriello speculated that compensatory factors probably keep the subsequent recruitment low. Dr. Fogarty agreed. According to the compensation model, there is a threshold below which the population must have immigration in order to recover.

Finally, a participant asked if the time-series models are more data-intensive than the other models discussed. The duration of the time series depends on the lifespan of the organism, so it may be better in the Guidelines to express a suggested minimum data set in life

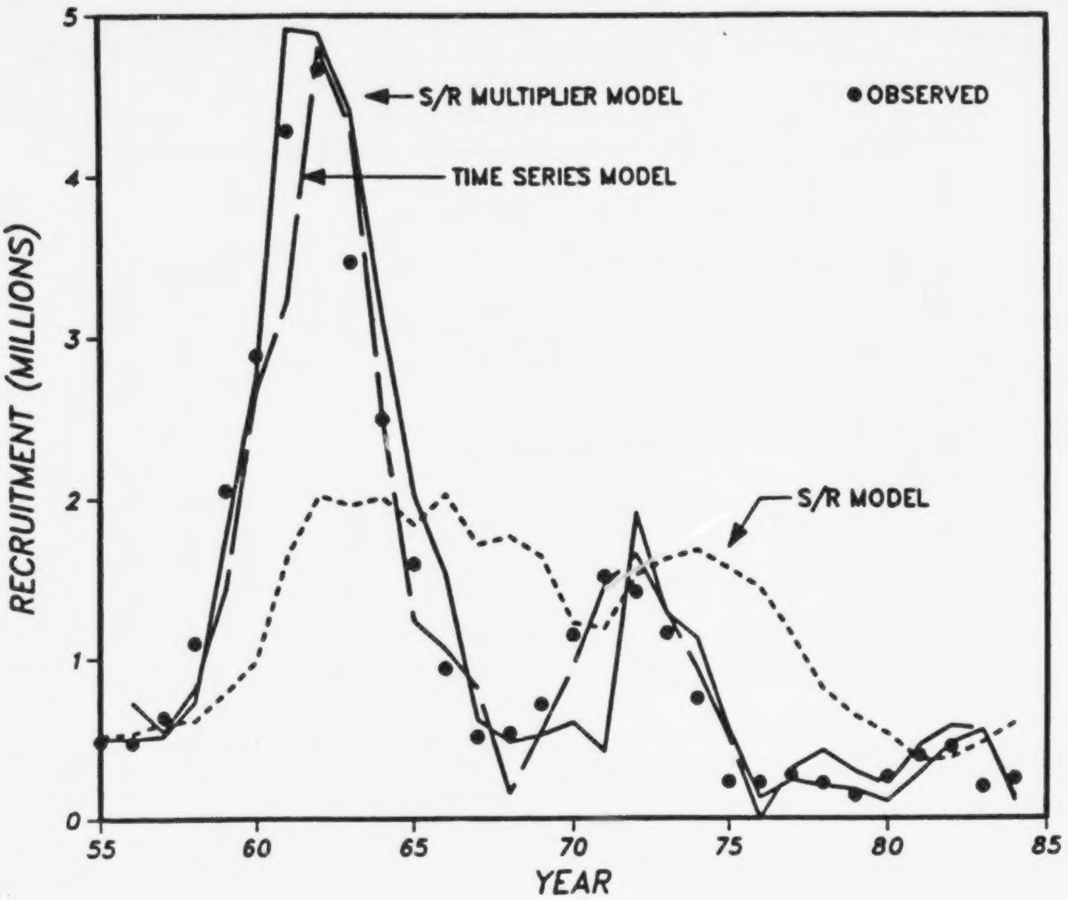


Figure D-5. Comparison of stock-recruitment (S/R), time series, and S/R multiplier models for plotting recruitment over time.

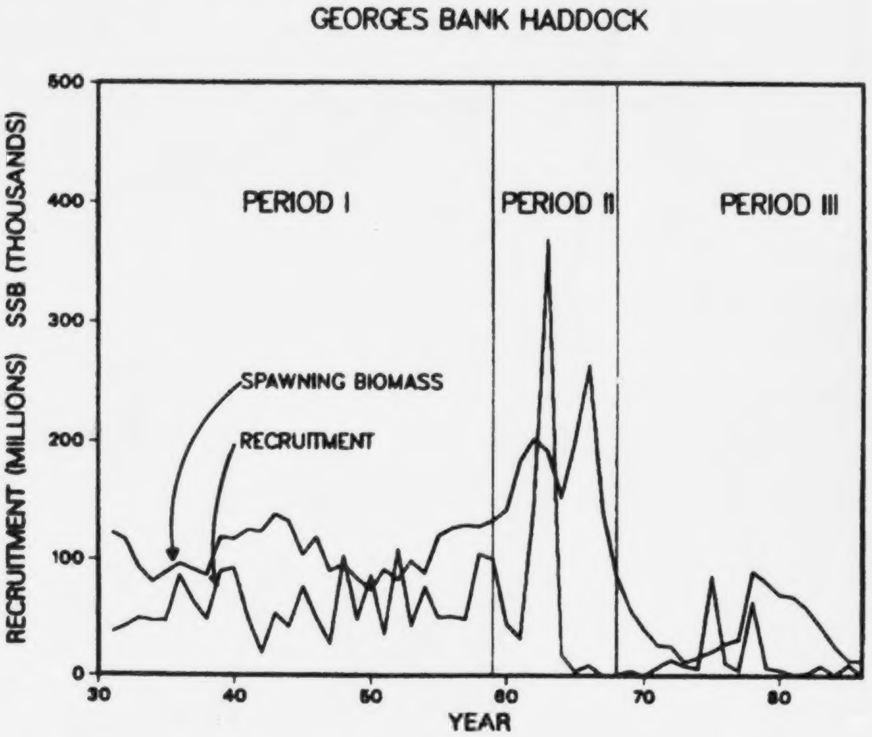


Figure D-6. Stock-recruitment model for Georges Bank Haddock, 1930-1985.

cycles rather than years. Dr. Fogarty reminded the group that if autocorrelation exists, then fewer independent data are available from a given data set.

Assessing Risks of Extinction with Structured Population Models

Lev Ginzburg, State University of New York, Stony Brook/Applied Biomathematics, Inc.

Dr. Ginzburg described three software packages that are used for estimating single-species populations' response to stress. The first, RAMAS/age, is an age-structured model, in which the age of the individuals that make up the species is taken into account in a simple matrix. RAMAS/stage is structured around life stages of the organism and unique or recurring events in the population. This type of model is very useful for projecting population effects in plants, because the life cycle is more stage-based than age-based. Finally, RAMAS/space models migration and occurrence patterns to predict population response to stress. This has been used to predict the probability of extinction for endangered species. All three produce an averaged picture of the population, including all variability over the projected time period, and the probability that the population will go below the critical abundance level (termed the "quasi-extinction level") within (or at the end of) that period.

RAMAS/age

Dr. Ginzburg provided printouts (available from EPA; see Appendix H) of the program screens used in RAMAS/age to guide the user in filling in the parameters needed to calculate population abundance. The program leads the user through a series of screens that first record the species name and general information and initial abundance and demographic schedules. Next it asks the user to choose a density dependence model and parameters, as well as set stochastic parameters (such as the number of replicates, demographic stochasticity, or population size, and coefficients of variability - survival, fecundity, and migration [which is additive only]). The program can then plot the data in any number of ways, for example, abundance as a function of time. After graphing the specified number of replicate runs, the program produces the mean population abundance plot, with 95 percent confidence limits and minimum and maximum values for each unit of time.

RAMAS/stage

RAMAS/stage incorporates the stages in the life cycle of the species of interest. For example, a tree population begins as a seed bank, then grows to seedlings, then saplings, then forms the understory, then the canopy, and then becomes timber harvest. Each of these stages is different in duration, which requires a much more complex model than the straight age progression used in RAMAS/age. RAMAS/stage can incorporate uneven residence times, variations in temperature and light, multidimensional structure within the population (young, diseased plants vs. old diseased plants), disparate time scales, complex transitions, and unique events during the time period into the population projection. When the timing and periodicity of stages and events are input, the program produces multiple matrices from the cyclic summary of the time period (see Figure D-7). These matrices are used to produce a graph similar to the RAMAS/age graph, plotting population abundance over time.

RAMAS/space

The last program models the interactions between multiple populations of the same species, an issue especially in the case of endangered species. The spatial structure of a population is important because of the bearing it has on the population's sensitivity to extinction risk, as well as its response to different stresses, such as fragmentation due to habitat loss, rechannelization, or construction. By studying the importance of spatial structure to populations, scientists may be able to better design wildlife reserves, and to answer the old question, which is better, a single large or several small reserve areas?

RAMAS/space is an improvement over occupancy models, which make several simplistic and unrealistic assumptions. The program produces a more accurate picture of probability of

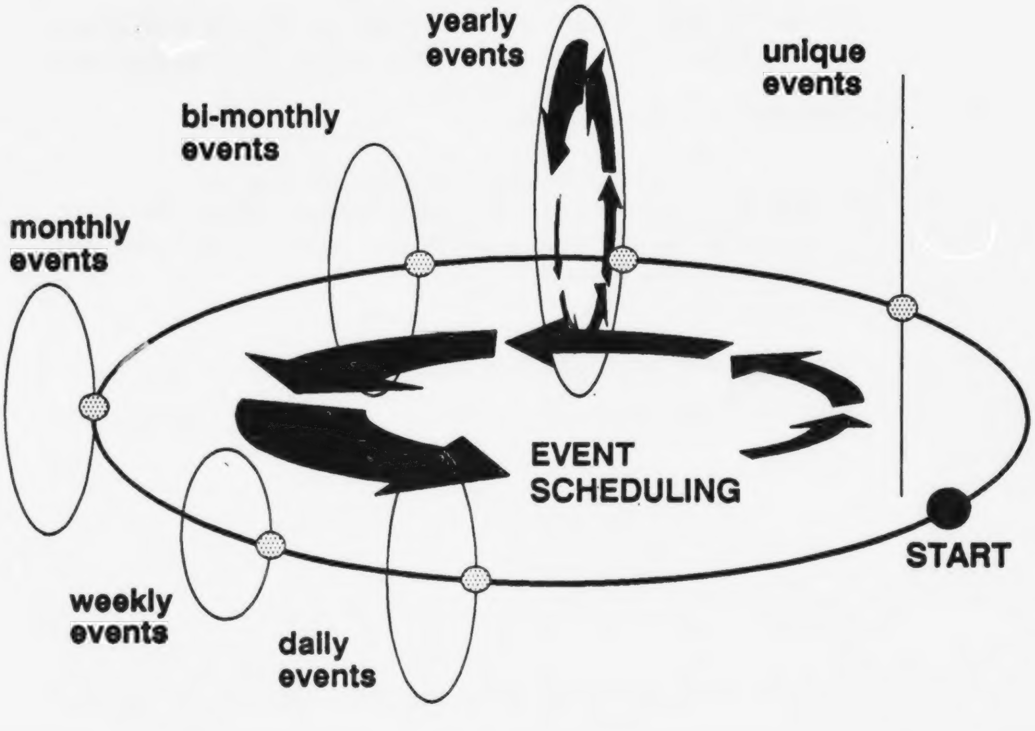

yearly events
unique events
bi-monthly events
monthly events
EVENT SCHEDULING
START
weekly events
daily events

Figure D-7. A schematic representation of the RAMAS/stage model, which incorporates both periodic and unique events.

extinction by incorporating information on the stochastic parameters for each portion of the population; the correlation between rates of growth among portions; and migration among patches, and how that migration correlates with the distance between portions. Through the model, the researchers were able to draw conclusions regarding the single-large or several-small question:

- For geographically close populations:
  - there are similar environmental patterns.
  - the correlation between the environmental variations is close to 1.
  - the probability of extinction is similar to that of a large population.
- For geographically distant populations:
  - there are almost independent environmental patterns.
  - the correlation between the environmental variations is close to 0.
  - the extinction probability is the product of local probabilities, and therefore much lower.

For every level of population abundance, increased migration decreases the extinction probability, whereas increased correlation between the sites increases the probability of extinction.

Discussion

An observer asked if there is an alternative to the models described during this colloquium. Dr. Ginzburg explained that because of the variation involved in the system, there is no other way to bring all of the factors together in a useful way. The models are tools for addressing the problems involved in predicting risk to populations, and are general so that they can be used in many ways. Dr. Mauriello suggested that the multidimensional model may be able to model an organism as a composite of many organs and biological processes, similar to the way a population is a composite of many organisms and environmental processes. Dr. Ginzburg agreed that once the correlations between toxic response and lipid content or size (for example) are determined, the model could be used in that way. There is a limit on the amount of data that can be incorporated into the matrices, but Dr. Ginzburg said that, due to the size of the data bases available, that limit has not proven to be a problem.

When asked, Dr. Ginzburg explained that sensitivity analysis is also possible with these programs, especially for large or nonlinear perturbations. In a current project, Dr. Ginzburg's group is performing a sensitivity analysis for fish populations in the Hudson River, determining the stages of the species most sensitive to power plant entrainment and fishing. The output will suggest a size limit for fishing in the river.

A participant asked whether the models have been validated, and how well the projections seem to hold. Dr. Ginzburg referred to the paper he submitted for the meeting (listed in Appendix H), explaining that validating probabilistic models requires extremely large data sets that include variance data as well as the mean data points. Sometimes half the available data are used to run the program, and the second half are used to validate the resulting projections. The best way to keep the projections reasonable, explained Dr. Ginzburg, is to carefully evaluate every assumption and, where uncertainty is involved, keep the assumptions relatively conservative.

Finally, a participant asked how RAMAS has been used, especially for management decisions. About 150 programs are in use across the country, mostly in academic settings as a teaching tool, 30 are in U.S. Fish and Wildlife Service and EPA labs, and 30 are used by utility companies to prepare environmental impact reports. Utility companies also use the programs as management tools, to show state or federal regulators that their plant's impact will be negligible. The output from the programs used in risk management decisions is usually the change in risk from baseline conditions to stressed conditions.

Uncertainty, Extrapolation, and Ecological Risk Assessment

Lawrence Barnthouse, Oak Ridge National Laboratory

Population Models in Risk Assessment

Dr. Barnthouse began his presentation by outlining the goal of risk assessment: to provide a sound, scientific basis for environmental regulation, in which the objectives and approach are always constrained by regulatory mandate and limited resources. Risk assessment does not find the truth or predict the future, but helps regulators make informed decisions. Risk assessment can:

- Quantify the magnitude and/or probability of adverse environmental changes.
- Compare different sources of stress, for example, impacts of fishing vs. a power plant.
- Permit balancing of competing risks (which should be regulated, the fishing or the power plant?)
- Compare control measures in terms of meaningful measures of environmental quality.

There are two categories of population models: those that quantify risks to specific populations, and those that provide meaningful interpretation of toxicity test data. The risk assessment model differs according to the desired endpoint of the assessment, whether evaluating the current status of the population or developing decision criteria for tiered toxicity testing.

A New Method for Using Population Models

Dr. Barnthouse described his research demonstrating the usefulness of population models for assessing ecological risks to fish from toxic chemicals, described in Barnthouse et. al., "Risks of Environmental Contaminants to Exploited Fish Populations: Influence of Life

History, Data Uncertainty, and Exploitation Density" (available from EPA; see Appendix H). The researchers chose two important sport and commercial fish with very different life histories, to develop models that could be used to:

- Develop a method for linking models to data typically available to regulators.
- Address important regulatory problems, such as whether life history influences susceptibility to toxic chemicals.
- Show how population models can be incorporated into existing regulatory framework.

Dr. Barnthouse and his collaborators developed a flow chart illustrating how, using extrapolation models, any of seven types of toxicity data can be used to estimate a concentration-response curve with accumulated uncertainty (represented by a band). Used in conjunction with a table providing extrapolation equations, the flow chart yields a species- and life stage-specific concentration response function (see Barnthouse et al., 1990, listed in Appendix H).

Dr. Barnthouse used this method along with a matrix-based population model to simulate recruitment for striped bass and menhaden exposed to trifuralin for 100-year periods and tabulated the percent of the population extinct during the period. When the percent reduction in recruitment over 50 years is plotted vs. the concentration of trifuralin, the uncertainty between the median, 5th percentile, and 95th percentile varies according to the type of data used. Figure D-8 shows the uncertainty associated with extrapolations using a full life cycle test for menhaden (top left); a life cycle test from sheepshead minnow extrapolated to menhaden (top right); an LC_{50} from another species (bottom left); and structure-activity analysis. By comparing the uncertainty associated with each type of test data at the EC_{10}, the risk assessor can decide which type of data is most useful for projecting population effects. Dr. Barnthouse listed the conclusions drawn from this exercise, and suggested that this information can be used to refine environmental toxicity testing and provide risk assessors with a way to estimate the risk of finding unacceptable effects associated with increasing contaminant concentrations.

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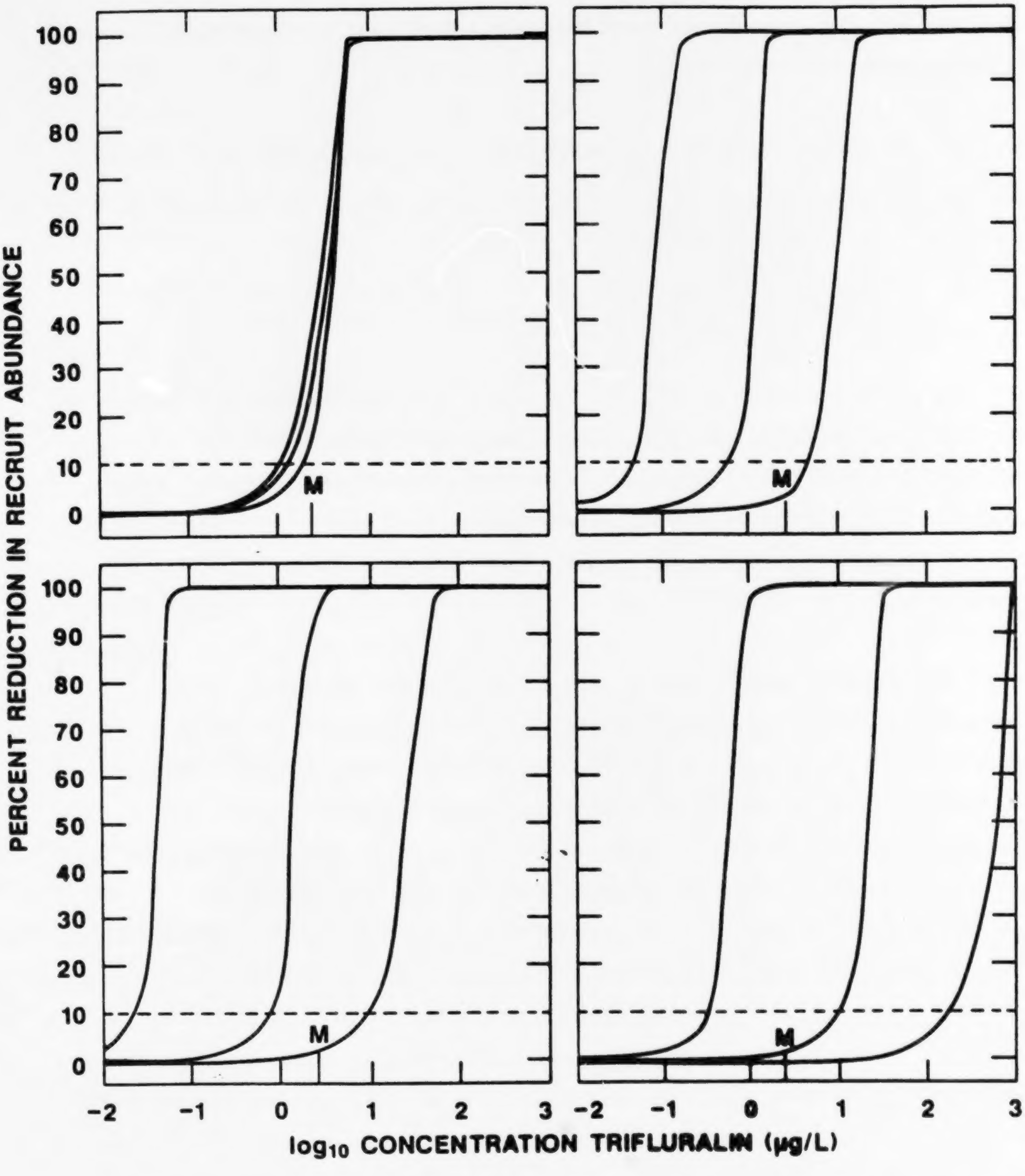

Figure D-8. Uncertainty bands associated with data from a full life cycle test (top left), a life cycle test from another species (top right); an LD_{50} (bottom left); and structure-activity analysis (bottom right).

This population modeling method is less sensitive than the ecosystem simulation model developed by Steve Bartell, because it does not take microorganisms into account. The ecosystem model is more sensitive than most models, noted Dr. Barnthouse, which raises the question of whether it is the model that is sensitive or the ecosystems themselves.

Future Developments and Needs

Few models exist that address spatially distant, multiple points of exposure, for example, the various points of mortality along the Hudson River; most models assume that the exposure takes place in one area, all at once. Chemical exposures also pose more problems for modelers than fishing or power plants do, because of the range of effects that occur, and that vary with temperature, oxygen levels, etc. One way to address these issues is to use models that project effects on the individuals (not age classes) in a population, from which the cumulative effects on the population can be estimated. Models must be developed that can take all variability in exposure and sublethal exposure into account - once the sources of that variability are identified through improved sampling and biomarker tests.

In closing, Dr. Barnthouse listed the characteristics of a model to be used for environmental regulation. The model must:

- Be understood by competent technical staff - no "black boxes."
- Be credible to the scientific community (especially EPA's Science Advisory Board).
- Use inputs and produce outputs that address a real regulatory problem.
- Be consistent with data and time constraints put forth in the regulations.
- Produce results that cannot otherwise be obtained.

To address some of these issues, Dr. Barnthouse is working to improve the software used in the modeling scheme and develop programs that will provide guidance to users. He stressed that it is up to EPA to develop and modify the decision schemes in risk assessment to incorporate models.

Discussion

Several participants had questions regarding the concentration-response curves with uncertainty bands shown above. One person asked why Dr. Barnthouse chose the EC_{10} as a comparison point for chronic responses. Dr. Barnthouse explained that below 10 percent reduction, the function tails off, with an increase in uncertainty as to what it does further down on the scale, making it harder to predict the response. When asked, Dr. Barnthouse stated that the steepness of the slopes between 10 and 90 percent reduction reflect the sudden change shown in the data. The uncertainty is shown on the horizontal scale for convention's sake; uncertainty is expressed as orders of magnitude across the horizontal axis.

A Work Group member asked if Dr. Barnthouse had tried this or any similar approach for terrestrial systems. He explained that, because there are few consistent testing protocols for terrestrial species, it is difficult to build a data set for developing models. Existing models for terrestrial systems do not address population effects. Most terrestrial models are adapted from aquatic systems, but are not as complex or as well developed as the aquatic examples.

General Discussion

Dr. Mauriello led the group in a discussion of several issues in population modeling: how to address the lack of data for terrestrial systems; retrospective risk assessments, for example, at Superfund sites; accounting for density-dependent factors in population response; deciding an acceptable level of risk using models; what can the models be used for, and what type of model is best; and finally, Dr. Mauriello provided some issues for future consideration.

Addressing Terrestrial Systems

Dr. Mauriello asked the speakers if they are using primarily the most complete data sets in choosing aquatic data. How can the models be used to address terrestrial populations?

Dr. Fogarty suggested that one can draw analogies between aquatic and terrestrial species on the basis of life history, for example between marine invertebrates and insects, which share similar reproductive strategies. Unfortunately, he continued, there has been an economic incentive for research and data-gathering for fish, whereas there has not been much support for terrestrial studies, except agricultural species. Dr. Barnthouse agreed that life history analogies are the key to using these models for terrestrial populations, but added that chemicals will pose more of a risk assessment problem on land than they have in aquatic systems. Dr. Weinberg agreed that the life cycles seem to have enough in common with terrestrial species to merit an attempt at modeling.

A participant added that the guidelines could state that there are general assumptions one can make given the life history of the species of interest.

Retrospective Risk Assessments

A participant asked if models could be used for specific species assessments at specific sites. Dr. Barnthouse explained that specially-fitted models would be needed, but it is possible. When asked, he said that it need not cost excess money or time to perform a special analysis in that way. Dr. Mauriello wondered if a hypothetical model would be needed at specific sites, for example, Superfund sites, if there is no time series data available. Dr. Barnthouse again stated that site-specific models have been developed, and a time series data base developed in 5 or 6 years. The group agreed that Superfund sites bring the assessor into the risk assessment process at a different point than predictive risk assessments, and should be addressed in the guidelines in relation to modeling in some way.

Density Dependence

The group discussed how density dependence should be incorporated into estimating population response. Dr. Ginzburg explained that as more density dependent factors are incorporated into population modeling, the response becomes more chaotic and difficult to predict. He suggested that, when there is weak or no density dependence observed in the population, it is better (for conservatism) to use a density-independence assumption. Compensation also becomes a greater factor in population response at low population densities.

When Is Risk Acceptable?

Dr. Mauriello asked the speakers if the models can pinpoint the levels of risk that are unacceptable, assuming that the goal is to preserve the population. All agreed that people put a limit on acceptable risk - once the unacceptable endpoint is chosen, the models can help determine what will produce that result, and therefore, how to avoid it. Dr. Ginzburg noted that the change in risk is usually more important to people, rather than absolute risk. Dr. Barnthouse stated that both types of models discussed at the Colloquium can be used to determine biological limits.

What Can the Models Do for Risk Assessors?

A participant asked if the models could be used to predict impact from a spill, given the site, species present, etc. All agreed that the models could prepare such a projection, incorporating existing life cycle data, hydrodynamic information, toxicity data, and so on. Dr. Ginzburg explained that modelers supply risk assessors with principles for use, but the assessors themselves must bring everything together to produce a working projection of the population response.

What Type of Model is Best?

Dr. Mauriello posed a final question to the speakers, asking whether it is better to characterize risk based on one large model, or several small models used together. All of the speakers agreed that smaller models incorporate less errors, and allow the risk assessor to mix and match models to find the "average truth."

Future Considerations

In the course of the general discussion, other issues were raised that the participants thought should be addressed in the Guidelines:

- How do migrating animals act when they arrive at their new site? Changes in eating or reproductive behavior may affect population responses.
- Models are yet to be developed that consider sublethal effects.

ATTACHMENT A

Agenda, Speaker List

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

POPULATION MODELING

Washington Information Center
401 M Street, SW
Washington, DC 20460

July 9, 1990

Agenda

10:00am	Opening Comments - David Mauriello, Office of Toxic Substances
10:15am	Using Matrix Population Models for Ecological Risk Assessment - James Weinberg, Woods Hole Oceanographic Institution
11:00am	Predicting Population Dynamics from Field Data - Michael Fogarty, National Marine Fisheries Service
11:45am	Lunch
1:00pm	Introduction - David Mauriello, Office of Toxic Substances
1:15pm	Assessing the Risks of Extinction with Structured Population Models - Lev Ginzburg, State University of New York, Stony Brook
2:00pm	Uncertainty, Extrapolation, and Ecological Risk Assessment - Lawrence Barnthouse, Oak Ridge National Laboratory
2:45pm	Break
3:00pm	Panel Discussion

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

POPULATION MODELING

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APPENDIX E

U.S. ENVIRONMENTAL PROTECTION AGENCY
Risk Assessment Forum Colloquium Series on Ecological Risk Assessment

Meeting with State Representatives

April 9, 1990

Introduction

This report summarizes the discussion at the meeting with state representatives, held April 9, 1990, in Washington, DC in the Washington Information Center, 401 M Street, SW. The invited state representatives and members of the workgroups charged with developing the new risk assessment guidelines discussed the scope, content, and approaches to performing ecological risk assessment. Although EPA guidelines are developed primarily to improve the quality of and promote consistency in EPA's own risk assessments, the Guidelines often have implications beyond the Agency. Therefore, the Guidelines Work group invited representatives from five states to share their experiences and perspectives with them. The state representatives spoke informally about ecological risk assessment in their states, and a general discussion followed, with issues presented for debate by the guidelines workgroups. These included:

- Do impact assessments and risk assessments serve the same purpose in the states? Should the Guidelines address both procedures?
- How do the states choose endpoints for the assessment?
- How do states address ecological relevance vs. social relevance when choosing endpoints?
- How are habitat considerations addressed?

Following is a summary of the presentations and discussion at the meeting, which was chaired by Dr. Patricia Cirone of Region 10. Attachment A to this report is the agenda and speaker list for the meeting; Appendix H lists references and handouts supplied by the states for the meeting.

Background

William Wood, RAF

Dr. Wood began by explaining the purpose of the RAF colloquium series: to provide support for the development of a new set of ecological risk assessment guidelines. He explained that the Risk Assessment Forum falls under the direction of the Risk Assessment Council, which answers directly to the EPA Administrator. The RAF is a group of 18 EPA scientists representing different programs in the Agency, and develops consensus from within EPA on risk assessment issues. The Forum also provides oversight to guideline workgroups. The current ecological guidelines workgroups deal with guidelines for assessing risk to aquatic populations, terrestrial populations, and aquatic communities. At this point, Dr Wood explained, the guidelines are in the very early stages of development, and any input is appreciated.

In 1983, the National Academy of Sciences reviewed risk assessment as it was performed in various federal agencies at that time, and developed the NAS "Red Book," which describes the risk assessment process and defines terms used. NAS also made recommendations to the federal agencies on carrying out risk assessments. One of the recommendations to EPA was to develop "inference guidelines" that describe acceptable approaches, provide guidance on new or alternative approaches, and list sources for information on the topic of concern.

In response, EPA initiated the guideline development process, which incorporates 2 to 3 years of initial development, intra- and inter-agency review, and final acceptance by the Administrator. The final, published guidelines are updated often to incorporate new information. The guidelines provide scientific policy that ensures consistency across the Agency, promotes quality in risk assessments, and supplies information to the public and other scientists. Guidelines stop at the risk characterization step in the EPA risk assessment process; risk management instruction is not provided.

Dr. Wood stressed that guidelines are not step-by-step cookbooks, strict rulebooks, or textbooks - guidelines assume a fundamental knowledge of the subject matter. This may be a problem in the ecological guidelines, as not many EPA scientists will be familiar with terms and procedures used in ecology. He added that not only the risk assessors, but also risk managers would need more specific information on ecology, so the ecological risk assessment guidelines should stress risk characterization more than other guidelines have.

Dr. Wood then introduced Dr. Cirone, who explained that the purpose of this meeting was to have the risk assessment theorists talk with the practitioners. The workgroups need to know if their guidelines will be useful to those actually performing the risk assessments. She then asked the EPA workgroup chairpersons to put forth issues specific to their particular guidelines that they would like to have addressed during the discussion. After that, the state representatives described how their state agencies use ecological risk assessment, and how they would use the Guidelines.

Aquatic Populations

Suzanne Marcy, Office of Water Regulations and Standards

Dr. Marcy listed several issues to be taken up at the meeting:

- How do the states deal with uncertainty in risk assessment? There is always experimental error, she explained, but more serious errors are due to uncertainties in extrapolation between species and from site to site.
- How are assessment endpoints chosen? Do state risk assessors select surrogate species? Do they look for direct or indirect effects on the organisms? How is habitat incorporated?
- How do states address the issue of ecological relevance vs. social relevance?
- Are impact and risk assessments different, or do they serve the same purpose in the states? Should the guidelines deal with both, and if so, how should they be treated differently?

Terrestrial Populations

Molly Whitworth, Office of Policy, Planning and Evaluation

Dr. Whitworth explained that the workgroups for the aquatic guidelines are far ahead of the terrestrial workgroup, primarily because of the relative lack of Agency experience in the area of terrestrial ecology. The group is considering combining the terrestrial and aquatic populations guidelines, thus assuring that wetlands are considered thoroughly. Presently, the terrestrial workgroup is researching different models for air and dermal exposure. The pesticides program at EPA concentrates on avian species in their assessments, however, this data may not be useful, as birds are very mobile, and therefore may not be the species most sensitive to chemical or nonchemical insult. It is also difficult to estimate the lifetime exposures of wild birds. She added that little information on toxicity testing is available on exposure to amphibian or herp species. Have any of the states pursued this? Dr. Whitworth was also interested in a discussion of how the states treat habitat alteration (whether a direct or indirect effect) in their assessments, and how land use concepts are incorporated.

Aquatic Communities

Michael Brody, Office of Toxic Substances

Dr. Brody expressed concern that the aquatic communities workgroup may not even proceed to prepare guidelines, but may submit a concept paper summarizing their findings instead. He wondered whether ecological risk could be defined by looking at community endpoints. Some issues to be considered are:

- Extrapolating from effects observed in critical species to community-level effects.
- Identifying community-level subchronic/sublethal tests in the lab or field that will give information on community level effects.
- Meshing the risk assessment process with the biocriteria/water quality criteria program by using risk assessment to find the effects associated with exceeding set limitations.

- Evaluating effects from non-toxic stresses, especially in wetlands; for example, measuring nutrient runoff and observing resulting changes in plant species present, sedimentation, and hydrology.

Some participants suggested that case studies incorporated into the guidelines would be more useful than a list of all possible endpoints, and asked if any states had performed community-level exposure or effects assessments that could be included as examples.

State Experiences and Perspectives

How Do the States Use Ecological Risk Assessment?

New Jersey Department of Environmental Protection. Dr. Joyce explained that in New Jersey's hazardous waste program, almost 10 years old, ecological risk assessments have not developed to the same level of sophistication as the human health assessments. The state is however, in the process of developing methods for ecological risk assessment. At hazardous waste sites, ecological risk is sometimes the only risk present, and so deserves attention. Under the three programs implemented by the hazardous waste program, there are different methods for determining appropriate clean-up levels--and the final estimations often differ among the methods by orders of magnitude. Dr. Joyce provided three examples of ecological risk assessment methodologies that have been presented to the DEP by various consultants:

- Analysis of Extrapolation Error (AEE). Provides a range of clean-up levels and the expected risk at each level. This is a quantitative method: the numbers are derived from toxicity tests and extrapolation between species and types of test.
- Toxicity Quotient. Compares environmental concentrations determined at the site to a benchmark concentration determined from toxicity testing.
- Mink and mallard risk assessments. Uses exposure and intake assumptions, and life cycle parameters to estimate a no-effect level.

Dr. Joyce explained that New Jersey is trying to develop methods for setting soil contaminant standards and sediment criteria limits for cleanups that incorporate the extent of bioaccumulation, etc. in order to consider human exposure from food and ground water contamination. The state is planning to develop a matrix, or a decision tree, for setting these standards.

Ohio Environmental Protection Agency. Mr. Beaumier explained that his division prepares assessments for individual dischargers using a "top-down/bottom-up" approach. Using laboratory-derived chemical criteria and wasteload allocations, the bottom-up portion predicts contaminant levels that will cause an adverse effect at a site. These numbers are then used to set regulatory concentrations. For the top-down portion, field tests are conducted to determine the actual effect. Mr. Beaumier explained that in this way, predictive results are constantly verified by observations of community effects in the field. This is a worthwhile exercise, because, for example, laboratory tests using completely dissolved metal samples in aquaria are not adequate predictors of the real fate and transport of the metals in a stream or river, where much of the metal is not bioavailable.

Ohio has recently revised its water quality standards to include numerical biocriteria. Mr. Beaumier explained that numeric criteria were necessary because risk managers often do not have a background in ecology or biology, and need an assessment method that nonbiologists can understand. To develop numeric criteria, the state was divided into ecoregions (areas having the same soil composition, land use, geology, etc.). Field surveys were conducted in the relatively cleanest streams to determine the freshwater communities present. Streams of various size and use were surveyed and categorized. Changes in habitat were also taken into account in the stream descriptions; for example, a "modified warm water" use designation was established to identify streams that have been dammed, affected by mining, or channelized. Numeric biocriteria, effective May 1, 1990, will play an important role in the way dischargers are regulated. In this scheme, if the biocriteria are met by the discharger, then there is probably no effect; however, if the biocriteria are exceeded, it is very likely that there is some problem, and near mixing zone field tests are used to verify this. If an effect is observed, whole effluent toxicity is evaluated. Mr. Beaumier reported that the whole effluent is tested about 30 percent of the time. If the whole effluent is determined to be causing the effect, then the state conducts a Toxicity Reduction Evaluation. If the field assessment contradicts the chemical-specific prediction of adverse effects, the state will reevaluate the predicted value, and perhaps use more sophisticated modeling techniques to develop chemical-specific recommendations.

The scenario could also go the other way: if an effect is seen that is not predicted, the discharger will be asked to find out what is causing the effect, and the numerical chemical limits may be lowered. Mr. Beaumier added that with this method, Ohio has found effects that would have gone unnoticed, especially effects due to nonpoint sources.

Michigan Department of Natural Resources. Mr. Duling described Michigan's Water Quality Program. The program estimates risk for terrestrial and aquatic life, and for human noncancer and cancer endpoints. (Michigan follows EPA's weight-of-evidence decisions to identify carcinogens.) There are three criteria calculated to noncancer endpoints -- Aquatic Chronic Value, Terrestrial Life Cycle Safe Concentration, and a Human Life Cycle Safe Concentration -- and an additional Cancer Risk Value for human cancer risk. The values for humans consider incidental water intake and fish consumption, while the terrestrial concentration considers only incidental water intake in the calculations. No target organism is chosen for the terrestrial value, although if site-specific information on impacts on the local wildlife is available, it can be incorporated into the calculations. The Aquatic Chronic Value is derived from bioassays and chemical-specific tests. The goal of aquatic chronic values is to protect 95 percent of the species for 80 percent of the chemicals. When all of the values are determined, the most restrictive is chosen as the Water Quality Standard. To date, approximately 45 percent of the limits are controlled by the aquatics value, 45 percent by the cancer risk value, and the remaining 10 percent are controlled by either the Human or Terrestrial Life Cycle Safe Concentration, but usually the latter.

The guidelines are separate from state rules, in that guidelines are nonenforceable, but are referred to specifically in the rules. Michigan does, however, have a commission in place that can overrule decisions made under the Water Quality Program although that has not happened to date. Under the guidelines, dischargers must supply a minimum data set, including a rat oral LD_{50}, a 48-hour EC_{50} or LC_{50} for a daphnid, and a 96-hour LC_{50} for fathead minnow or rainbow trout. The Department of Natural Resources derives acute and chronic values from these concentrations, using application factors, and a cancer risk value of 1 and 100,000. Michigan allows industry to conduct site-specific tests beyond those specified in the minimum data set requirements in an attempt to raise the final Water Quality Standard. Preexisting data cannot be discarded without proof or cause, regardless of additional data supplied by the manufacturer.

The state is also joining with the Great Lakes Initiative (which includes EPA Regions 2 and 5, EPA Headquarters, and the Great Lakes states) to develop regional approach to developing basin-wide water quality standards, including wildlife protection numbers.

Michigan is in the process of establishing an ecoregion system somewhat like Ohio's; sediment toxicity testing in the laboratories is also in the developmental stages. The state is also working on some damage assessments in the Kalamazoo River and Waukegan Harbor for the Department of the Interior.

Washington Department of Ecology. Dr. Blakley described several examples of risk assessment methods used under various programs in Washington State (detailed descriptions available from EPA; see Appendix H).

First is the 2010 project, in which human and ecological risk assessments were used to prioritize problems in the state for funding allocations within the Department of Ecology. The analysis included identification of all available data on the stressors, sources, pathways of exposure, receptors, and effects, which were then compiled into a report for each problem. A committee then ranked the problem using the information from that report, using a scoring system based on intensity of the stress, reversibility, cumulative nature and extent of the effects, the sensitivity of the receptor(s), the productivity or uniqueness of the ecosystem affected, and the uncertainty associated with the available data base.

The second project is the state program for comparative risk analysis for dredged material disposal. This process uses the NAS risk assessment paradigm to estimate ecological risk from disposal of contaminated dredged material in deep water, in shoreline fill, and on land. Contaminant concentration, fate and transport, and dose-response information from sediment bioassays performed on local indicator species are included in the estimation of risk, which is reported ultimately as a qualitative, short-term fate, or long-term fate estimate of risk using models.

A third way risk assessment is used in Washington is in the Apparent Effects Threshold (AET) Approach to Defining Sediment Quality Values. Chemical-specific sediment quality values "reliably predict the presence or absence of adverse biological effects" from contaminated sediments. This is not a site-specific approach, but rather employs concentration data from an array of stations and biological tests on surrogate species ("biological indicators") to derive AET values. If a sediment has chemical concentrations below all of the AET values for an indicator, it is assumed that sediment will have no effect on that species. Dr. Blakley explained that this has been a very reliable way to identify possible sources of effects. To date, less than 5 percent of the stations that have shown an effect have had chemicals below their specific AET values. This method is specific to decisions on sediment toxicity; however, the Department of Ecology thinks that these values help to establish a "preponderance of evidence" for identifying chemicals of concern.

Dr. Blakley also presented an alternative methodology for deriving sediment standards which was proposed as alternative to the chemical-specific sediment standard approach. This method starts with a risk management goal, and works backward to do a site-specific risk assessment. Then economic and cost-risk assessments are performed.

The fourth and last risk assessment method used in Washington is to provide hazard rankings of contaminated sediment sites for subsequent cleanup. The method scores human health hazard and ecological hazard from contaminated sediment sites separately. The ecological assessment takes quantitative information on the waste characteristics, site characteristics, and affected resources into account along with qualitative information on off-site impacts and potential water column impacts. The Department is planning on field testing the ranking system during 1990.

Wisconsin Department of Natural Resources. Dr. Sullivan outlined Wisconsin's various state programs, and how they use risk assessment. The Air Program is entirely technology-based, he explained, and does not use risk assessment. Protection of human health is the only endpoint used to determine the regulatory decisions in that program. The Water Supply and Ground-Water Programs use human health risk assessment only. In the Solid Waste Program, risk assessments are performed by contractors charged with cleaning up hazardous waste sites; these are most often only human health-related, and the contractors tend to ignore state guidelines for risk assessment. Within the Surface Waters Management Program, there are both point source and nonpoint source programs; however, the nonpoint source program is voluntary. The state surface water quality standards are implemented through the point source regulatory program. The surface water standards provide protection for humans, aquatic life, and wildlife. Ecological risk assessment forms the basis of the surface water standards.

In the surface water quality standards program, the human health risk assessments are taken straight from EPA, while the ecological risk assessments are conducted by the state. To date, most work in protecting wildlife from suspected toxic impacts has focused on aquatic wildlife (animals such as mink and obligate fish-eating birds, like terns). Monitoring data confirm that little if any toxic exposure occurs in upland terrestrial wildlife, even in the most contaminated areas.

Dr. Sullivan described an exposure assessment performed in his state a number of years ago, in which food chain bioaccumulation was taken into account. Terrestrial food-chain modeling of dioxin uptake from invertebrates to a native songbird was performed to determine the effects on avian reproduction. The Department of Natural Resources was able to predict the exposure to within an order of magnitude of the exposure observed in the field. When asked, Dr. Sullivan stated that he did not think his state could perform an exposure assessment on an amphibian with the data base available. Dr. Cirone asked if the states were missing a lot of exposure data by ignoring the contribution from air. Dr. Sullivan thought that air contamination does not contribute significantly to terrestrial wildlife exposure. Atmospheric deposition of toxics in the Great Lakes and large lakes, as well as rain-fall, may lead to lake acidification; these factors, however, are taken into account in the state's assessments.

A participant asked if the states saw any impediment to their using ecological risk assessment in their programs. Dr. Joyce asked that ecological assessment not turn into an endpoint in itself, but only be applied in a site-specific manner. Flexibility is the key, she stressed.

How Would the States Use the Guidelines?

New Jersey Department of Environmental Protection. Dr. Joyce stated that New Jersey would find the guidelines very useful, and would use them to establish clean-up goals, perform baseline analysis, and analyze alternatives for site cleanups.

She also asked for input on some other issues being addressed in her state; for example, New Jersey is currently developing guidelines for contractors that provide minimum requirements for cleanup, and assessing on- and off-site discharges to wetlands, since about half of the state's contaminated sites are wetlands. She stressed that the state is working with very little information at this point, and needs some guidance from EPA.

Dr. Joyce said that she is presently reviewing New York State's draft (12/28/89) *Habitat-Based Assessment Guidance Document for Conducting Environmental Risk Assessments at Hazardous Waste Sites* (available from EPA; see Appendix H). The state's scheme includes site description, resource characterization, hazardous threshold identification, and monitoring steps.

Washington Department of Ecology. Dr. Blakley said that he would like to see a clear approach to ecological risk assessment spelled out in the guidelines, with some consideration of the ecological effectiveness, or effectiveness of the predictions from the methods proposed. He then summarized some messages from Dr. Keith Phillips, also from the Washington Department of Ecology, who was unable to attend the meeting:

- In evaluating risk assessment methodologies, it is important to look at the goal of the analysis - the risk management endpoint should have some impact on the risk assessment, and a range of approaches should be available.
- Risk assessment methods should be all-encompassing, including multimedia, and all trophic and ecological levels of organization and taxa.
- Consider methods other than the NAS paradigm to estimate risk; for example, consider the empirical approach used in calculating AETs in Washington.

A participant asked if Washington was holding the ecological risk assessment method to a higher standard than the human risk assessment by asking for an effectiveness evaluation of the guideline methodologies. Another participant agreed, and said maybe the guidelines could be judged for management effectiveness instead, or whether the guidelines help risk managers make decisions. Dr. Blakley persisted, saying that he would like to have some idea of what the assessment means in the field: when one regulates based on mallard tests, how many other species are really being protected? Perhaps a retrospective study at a site to evaluate the predictions would be worthwhile, he stated. He also asked the workgroups to address Type 1 and Type 2 errors.

Wisconsin Department of Natural Resources. Dr. Sullivan was concerned that the ecological risk assessment guidelines, when finished, would merely sit on the shelf for lack of staff to deal with ecological risk assessment. He thought that, unless these assessments are written into existing EPA-mandated programs, most states will not use them. He listed some information his state and other could use:

- Guidance for dealing with congeners of PCBs, dioxin, and chemical mixtures, perhaps using toxic equivalency data.
- More information on bioavailability, metals speciation, etc. so that they can be incorporated into the risk assessment.

- More bioaccumulation factors coming from EPA.
- Information on which terrestrial and aquatic species to use as surrogates.

Mr. Beaumier and Dr. Joyce agreed that more information was needed on the bioavailability of chemicals in the environment. Dr. Joyce thought that the guidelines could list the site-specific data that are needed to perform a risk assessment. Dr. Cirone stated that the workgroups see the guidelines as a place to identify what is needed - not necessarily to dictate new procedures, but to put methods already used in the states into a general scheme.

Dr. Blakley wondered how much money and time it would take to do these assessments, and asked the workgroups to take that into consideration. Mr. Beaumier argued that ecological risk assessments performed in his state are as cost effective, if not more so, than the chemical analyses.

The group discussed whether guidelines within EPA have impact on state regulations. EPA staff explained that the nature of guidelines is not to serve as regulatory documents, but should serve to make ecological risk assessment practices consistent across programs, and provide a baseline to which everyone performing assessments can compare their own process.

Discussion Session

The group considered the following issues in an open discussion:

- Should the guidelines workgroups use the NAS risk assessment paradigm as is, adapt it to fit ecological risk assessment more easily, or develop a new paradigm?
- What ecological endpoints should be proposed, considering various factors such as ecological vs. social significance; available population measures such as mortality and reproduction rates; possible community measures; and the chosen endpoint's implications for risk management?

- How should exposure be assessed? Several factors must be taken into account, such as temporal and spatial variation; recovery and resilience of the ecosystem; habitat degradation and modification; multimedia analysis at all trophic levels; and bioavailability, bioconcentration factors, and toxicity equivalents.
- How should application factors and safety factors be chosen to account for uncertainty in measurement and extrapolation?
- How should statistical significance be incorporated; should the uncertainty be expressed quantitatively or qualitatively?
- Should the risk assessment be applied independently, or should weight of evidence be considered?

The NAS Paradigm

EPA staff described a portion of the discussion from the first colloquium regarding the choice of a paradigm for carrying out ecological risk assessment. The invited speakers, Drs. Barnthouse, Suter, and Harwell, expressed varying degrees of satisfaction with the human health risk assessment paradigm as it applies to ecological risk assessment. Some present suggested that ecological risk assessment procedures could fit into the existing scheme; however, others stated that if the terminology in the paradigm is made too general, the information meant to be collected in the process is lost. One participant added that the Guidelines could put forward a tiered approach, starting from the general and moving toward more specific analysis. The state representatives did not have any comment on the paradigm as it stood.

Ecological Endpoints

The state representatives were asked how they address the issue of social relevance vs. ecological relevance for endpoints to the risk assessment. Dr. Blakley stated that his state would be unable to perform the risk assessment without proving that the endpoint looked at is significant to humans in itself, or is an indicator of an effect on something significant to humans. Mr. Duling explained that his state protects the untested species - numbers from assessments made on indicator species are "driven down" using safety factors to protect the untested, possibly more sensitive species. Dr. Blakley responded that it was unlikely that this would affect the state criteria for sediment because the numbers from their assessments already are quite low.

Dr. Sullivan stated that the goal of the wildlife protection standards in Wisconsin is to maintain a sustainable reproductive population. This means that minor effects unrelated to maintaining the population, such as kidney tubule lesions, may be overlooked in the assessment.

Dr. Joyce explained that New Jersey is trying to move away from using lethality as the sole endpoint evaluated in ecological risk assessment. Furthermore, the program does not focus exclusively on rare and endangered species, but includes an assessment of representative species. Predictive population effects assessments using existing studies are used most frequently, but it depends on the site under study. Dr. Joyce and Mr. Duling brought up the issue of using mink as a surrogate species in risk assessments due to its known sensitivity to some contaminants (e.g., PCBs).

Exposure Assessment

Habitat degradation was presented as a possible endpoint in the risk assessment. Mr. Beaumier described Ohio's Qualitative Habitat Evaluation Index, which gives a good picture of the aquatic habitat and also provides a way of ranking risks.

One participant asked if the states consider reversibility and ecosystem resiliency in their risk assessments. Mr. Duling explained that one violation is enough to allow the state to regulate a discharger, and recovery is not assumed. Dr. Sullivan explained that his state follows EPA guidelines for averaging measurements. His state also takes some lifetime exposure into account. Dr. Blakley said that Washington does take some recovery and natural cleanup processes into account in hazardous waste clean-up plans. Dr. Joyce agreed - New Jersey decides during the site assessment whether the problem will "fix itself" without cleanup action.

Dr. Cirone asked if anyone would take recolonization predictions supplied by dischargers into account. Dr. Sullivan and Mr. Duling said that their states would not allow anyone to discharge based on predictions.

Uncertainty Analysis

EPA staff asked if the state representatives prefer guidelines that propose quantitative uncertainty analysis. The representatives encouraged EPA to omit any reference to quantitative uncertainty analysis or statistical significance of the final risk from the Guidelines. Mr. Duling explained that state regulators would appreciate support from EPA in the form of a statement that supports professional judgement, rather than statistical analysis, in evaluating risk assessments.

EPA staff asked what the states do need as far as documenting the uncertainty in extrapolations. Mr. Duling said that Michigan already does document the uncertainty in its assumptions.

ATTACHMENT A

Agenda, Speaker List

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

MEETING WITH STATE REPRESENTATIVES

Washington Information Center
401 M Street, SW
Washington, DC 20460

April 9, 1990

Agenda

10:00am	Opening Remarks - William Wood, Risk Assessment Forum
10:20am	Issues for EcoRisk Guidelines - Guidelines Work Groups Aquatic Populations - Suzanne Marcy Terrestrial Populations - Molly Whitworth Aquatic Communities - Michael Brody
11:00am	State Experiences and Perspectives - Kate Joyce, NJ DEP - Ray Beaumier, OH EPA - Linn Duling, MI DNR
11:45am	Lunch
1:00pm	State Experiences and Perspectives (continuation) - Keith Phillips, WA Dept. of Ecology - John Sullivan, WI DNR
1:30pm	Open Discussion
4:00pm	Conclusions
4:30pm	Adjourn

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

MEETING WITH STATE REPRESENTATIVES

Invited Representatives

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APPENDIX F

U.S. ENVIRONMENTAL PROTECTION AGENCY
Risk Assessment Forum Colloquium Series on Ecological Risk Assessment

Meeting with Federal Representatives

May 14, 1990

Introduction

This report summarizes the discussion with federal representatives, held May 14, 1990, in Washington, DC, in the Washington Information Center, 401 M Street, SW. The invited federal representatives and members of the work groups charged with developing the new risk assessment guidelines discussed the scope, content, and approaches to performing ecological risk assessment. The federal representatives spoke informally about ecological risk assessment in their agencies, and provided some input to the Guidelines Work Groups regarding principles and approaches that could be incorporated into the Guidelines. The representatives were asked to address the following topics:

- How do other federal agencies use ecological risk assessment?
- Is some form of the NAS paradigm used?
- How are endpoints selected and measured?
- How do other agencies estimate hazard?
- How do they characterize uncertainty?

The following is a summary of the discussion at the meeting chaired by Dr. Molly Whitworth of EPA's Office of Policy, Planning, and Evaluation. The speakers' responses to EPA's issues are described under topic headings; the general discussion is also divided by issue. Attachment A includes the agenda and speaker list for the meeting; Appendix H lists the references and handouts provided by the speakers.

Background

William Wood, RAF

Dr. Wood explained that the purpose of the colloquium series is to provide support for the development of a new set of ecological risk assessment guidelines. He explained that the RAF falls under the direction of the Risk Assessment Council, which answers directly to the EPA Administrator. The RAF, which is comprised of 18 EPA scientists representing different programs in the Agency, develops consensus on risk assessment issues. The Forum also provides oversight to technical panels, special short-term subcommittees, and guideline work groups. The current ecological guidelines work groups deal with guidelines for assessing risk to aquatic populations, terrestrial populations, and aquatic communities.

In 1983, the National Academy of Sciences (NAS) reviewed risk assessment as it was performed in various federal agencies at that time, and developed the NAS "Red Book," which describes the risk assessment process and defines risk assessment terms. NAS also made recommendations to federal agencies for conducting risk assessments. NAS recommended that EPA develop inference guidelines that describe acceptable approaches, provide guidance on new or alternative approaches, and list sources for information on the topic of concern.

In response, EPA initiated the guideline development process, which incorporates 2 to 3 years of initial development, intra- and inter-agency review, public comment, and final acceptance by the Administrator. The final, published guidelines are updated often to incorporate new information. The guidelines provide scientific policy that ensures consistency across the Agency, promotes quality in risk assessments, and supplies information to the public and other scientists. Guidelines stop at the risk characterization step in the EPA risk assessment process; risk management guidance is not provided.

Dr. Wood stressed that guidelines are not step-by-step cookbooks, strict rulebooks, or textbooks; rather, guidelines assume a fundamental knowledge of the subject matter. This may be a problem in the ecological guidelines, because few EPA scientists are familiar with terms and procedures used in ecology. The guidelines serve as a bridge between raw data and a characterization of the risk posed by a stress. The risk manager then takes that risk characterization and develops a regulatory decision based on economic, regulatory, and social factors. What constitutes a social decision has been discussed in past meetings. He explained that the decision to close down a factory is a social decision, while the choice of the species of interest for risk assessment is not.

Dr. Whitworth introduced the work group chairpersons, who outlined the current state of the guidelines and some of the issues they are dealing with.

Work Group Issues

Aquatics Population Work Group

Suzanne Marcy stated that the Aquatic Populations Work Group is using data from assessments of individual organisms to predict population response. The Work Group now has a working draft of the guidelines. She stated that the Work Group (in fact, all of the Work Groups) would appreciate information on the following topics:

- Extrapolations from species to species, and extrapolations from effects measured in individuals to effects on the population at large - issues that the human health risk assessors do not address.
- Whether the guidelines should recommend quantitative or qualitative assessments.
- Expanding hazard identification to include receptor characterization, which goes beyond the NAS paradigm.
- How habitat characteristics change the exposure assessment.

Aquatic Communities Work Group

Michael Brody, of the Aquatic Communities Work Group, explained that his group is preparing a concept paper, rather than formal guidelines, which will examine the growing body of mesocosm data and results from single species tests to determine whether mesocosm studies can be applied to the prediction of community response to a stress. The Work Group is attempting to determine the types of information provided by mesocosms that are not provided by single-species tests. Superfund community case studies, which serve as retrospective studies of the impacts of specific stresses on the community structure, are also being considered as tools for risk assessment, as they may provide better understanding of exposure fields and species inter-relationships in the real world.

Terrestrial Populations Workgroup

The Terrestrial Populations Work Group has a working outline and is preparing draft guidelines, explained Anne Sergeant. The group is hindered by the lack of data available on terrestrial systems. Only EPA's Office of Pesticides Programs has addressed the issue, but in a limited area. Assessing habitat destruction and alteration is one area that the Work Group is pursuing. This issue overlaps with those being considered by the Aquatic Populations Workgroup, especially in wetlands research, and the two Work Groups may be combined to produce a single Guidelines.

Issues in Federal Risk Assessment

Each of the federal agency representatives described how risk assessments (if any) are carried out in his or her organization. The descriptions are grouped below according to the issues proposed for discussion by EPA. (Not all of the representatives addressed every question.) It should be stressed that, while the representatives provided some insight into procedures used in their Agencies, their responses should not be taken as official statements by those agencies. The federal participants were:

Tom Dillon
U.S. Army Corps of
Engineers

Sarah Gerould
U.S. Fish and Wildlife
Service

Gary Heinz
U.S. Fish and Wildlife
Service

Mike Harrass
U.S. Food and Drug
Administration

Denny Buckler
U.S. Fish and Wildlife
Service

John Bascietto
Department of Energy

Ali Alavi
U.S. Army

Larry Gross
U.S. Forest Service

Tom O'Connor
National Oceanic and
Atmospheric
Administration

Bill van der Schalie
U.S. Army

David Engel
National Marine Fisheries
Service

The questions posed included:

- How do other agencies use ecological risk assessment (page F-7)?
- Do they use some form of the NAS risk assessment paradigm (page F-11)?
- How do the agencies estimate hazard to organisms and their supporting environment (page F-13)?
- How do they estimate or monitor exposure (page F-16)?
- How do they predict population- and community-level effects (page F-17)?
- How do they choose and measure endpoints and species of concern for the risk assessment (page F-20)?
- How do they characterize uncertainty? Are the results from the assessment qualitative or quantitative, and to what degree (page F-22)?
- Are the same procedures applied to both chemical and physical (i.e., habitat modification and destruction) stressors (page F-25)?

Additional issues were discussed in a general session at the end of the presentation:

- What is the role of the ecological risk assessment guidelines, and ecological risk assessment in general (page F-26)?
- Should post-assessment monitoring be recommended in the Guidelines (page F-26)?
- Is ecological risk assessment feasible with current technology (page F-27)?

Federal Perspective

How Do Other Agencies Use Ecological Risk Assessment?

U.S. Food and Drug Administration (FDA). FDA uses the basic paradigm of risk assessment to determine the environmental impact of new food additives (including food packaging) and animal and human drugs. FDA's environmental review is done to comply with the National Environmental Policy Act (NEPA) and is similar to EPA's Office of Toxic Substances' pre-manufacture review. FDA usually concludes that there will be no impact from a material, based on a comparison of the expected environmental exposure with concentrations associated with effects.

FDA does not require environmental fate or effects testing for every chemical it regulates. Data from a single species may be acceptable, whether the species is known to be sensitive or not. Usually, FDA requests data only when specifically needed, and justifies why a particular test is necessary for the assessment.

One participant asked if the policy of "innocent until proven guilty" produces less stringent regulations from FDA because the more tests that are performed, the more likely it is that an adverse effect will be found. Dr. Harrass explained that the environmental review is only one element of the final FDA decision; the human health assessment is FDA's primary concern. Dr. Harass said that, where FDA has assessed the same material as EPA, FDA's review was as stringent as EPA's, if not more stringent. FDA's authorizing statute and implementing regulations tend to be risk-averse, not risk-benefit, approaches.

National Marine Fisheries Service (NMFS). Risk assessment in the southeastern U.S. focuses on permits that will result in habitat alterations and impacts that will affect important living marine resources. The research is primarily concerned with physical alterations in the environment (such as dredging, waterways diversion, or coastal development such as marinas and real estate), rather than chemical exposures (although some research includes the effects of metals contamination). Most of the assessments are in response to day-to-day crises as well, so long-term predictions are not considered. The program has three components:

- Basic habitat research to characterize fish food webs, metals speciation, and habitat status and value.
- Applied habitat research, including national monitoring programs, mitigation follow-up studies, and fish survival, growth and reproduction studies.
- Consultation with the environmental constituency - state and federal agencies, and sport and commercial fishing organizations.

U.S. Army. The Army, as a regulated agency, performs environmental risk assessments, primarily on materials unique to the military, to fulfill legal requirements under NEPA and to determine clean-up levels for hazardous waste site remediation. Most of the hazardous waste site assessments are driven by potential human health effects. The Army also develops its own Water Quality Criteria for Army-unique materials. (Dr. van der Schalie explained that the Navy also performs assessments under NEPA and for hazardous waste sites.) The Army and Navy may fund EPA research laboratories for ecological effects assessment research, and the three military branches (Army, Navy, and Air Force) are conducting a joint study on methods for ecological risk assessment at hazardous waste sites.

The Army is also a regulatory agency. The U.S. Army Corps of Engineers issues permits for dredge and fill operations in the ocean and inland waters of the United States under Sections 103 of the Ocean Dumping Act (PL 92-532) and 404(b)(1) of the Clean Water

Action (PL 92-500), respectively. These permits are issued using criteria developed in conjunction and in consultation with EPA. Disposal of dredged material is not allowed if the potential for "unacceptable adverse impacts" is demonstrated. Potential impacts are evaluated using procedures developed jointly with EPA. These procedures are tiered and utilize an effects-based approach. The effects-based approach is more appropriate for evaluating complex mixtures such as sediments than one based on chemistry because: 1) effects produced by all contaminants present in the mixture, both detected and undetected, can be measured; 2) potential chemical interactions within the mixture are included in the assessment; and 3) differences in contaminant activity (i.e., bioavailability) are accounted for. Most tests measure percent survival in appropriate test species although development of chronic sublethal sediment bioassays is the focus of much current research within the Corps. Based on this strategy, only about 5 percent of the material that is dredged each year (350-500 million cubic yards) is considered unacceptable for unrestricted, open-water disposal.

A participant asked Dr. Dillon how the Corps decides which dredging projects merit an ecological risk assessment. He responded that because there is so much variation among types of dredged material, project locations and disposal sites, the decision is made on a case-by-case basis.

U.S. Fish and Wildlife Service (FWS). FWS is increasingly involved in site investigations at hazardous waste sites to determine clean-up goals for certain species (usually endangered or threatened species, or migratory birds, or other species as defined by law). FWS also performs assessments for clean up, land acquisition, and wetlands restoration at contaminated refuges and other federally managed lands Often FWS must place a dollar amount on the damage. These assessments are performed under NEPA, CWA, and Superfund (National Resource Damage Assessments). Finally, FWS acts in an advisory capacity to other agencies, since it is not a regulatory agency, and performs impact assessments for dredging, oil spills, and pesticide use. Most of these assessments are retrospective, assessing the damage or impact from stresses already present, and involve interpretation of data obtained by monitoring programs such as the National Contaminant Biomonitoring Program, or site-specific studies and surveys. The assessments stress field studies, which may not be as feasible for EPA, added Dr. Heinz.

National Oceanic and Atmospheric Administration (NOAA). NOAA performs monitoring surveys across the country to determine average contaminant levels. The Administration avoids including hotspots in their regular monitoring since they are not representative, but do use those areas for study. Through effects assessments, NOAA hopes to determine how much stress a system can take - and that requires knowledge of the location and extent of the stresses already present. NOAA is a resource agency, and is responsible for estimating acceptable cropping of sport and commercial fisheries. NOAA has developed population models to accomplish this task which could also be used for chemical stressors as well.

U.S. Forest Service. The Forest Service in the Department of Agriculture uses a combined ecological and human health risk assessment to determine the impact of land management practices (especially vegetation management using herbicides on clear-cut land) in Forest Service lands.

U.S. Department of Energy (DOE). DOE has been placed in the role of risk assessor due to a number of Superfund sites and waste management facilities under the Department's jurisdiction. DOE is also subject to the environmental impact statement requirement under NEPA for all large building projects. DOE incorporates ecological risk management into all steps of a Superfund remediation project, from the preliminary assessment, where a "mini" risk assessment is performed, to the choice of the remediation method.

Is Some Form of the Risk Assessment Paradigm Used for Ecological Risk Assessments?

Food and Drug Administration. FDA uses a simpler risk assessment scheme than that suggested by NAS. FDA estimates a toxicity criterion concentration using all available data on organisms representative of those potentially exposed in the environment. The criterion concentration is either a no-observed-effect concentration from chronic tests or 1/100th of an EC_{50} from an acute test on the most sensitive relevant species tested (as dictated by regulations). The criterion concentration is then compared to the expected exposure levels. If the actual exposure is predicted to be below that expected to cause an effect, then the material is presumed safe for manufacture. When no data are available for the subject material, FDA looks for toxicity data on similar materials. FDA has not used quantitative structure-activity analyses routinely or extensively.

National Marine Fisheries Service. The Habitat Conservation Division of NMFS recommends measures to minimize impacts through the use of a hierarchial approach similar to that developed by the Council on Environmental Quality in response to NEPA. This is in keeping with NMFS policy of addressing habitat alterations by minimizing impacts and the loss of submergent and emergent fishery habitat. The strategic habitat conservation guidance policy assists and guides habitat managers and researchers.

U.S. Army. While the effects-based approach utilized by Corps does not follow the Risk Assessment paradigm precisely, it does contain similar critical elements. For example, the Corps conducts an initial evaluation which is analogous to Hazard Identification. Here, critical pathways and target species are identified. Exposure Assessment in the aquatic environment is concerned primarily with determining whether impacts will be associated with the water column or the benthic environment. In contrast with traditional risk assessments, the Corps focuses on exposure-response relationships during Effects Assessments instead of chemical-specific dose-response relationships. The reasons for this strategy are the same as those that justify the effects-based approach.

Once the technical information is gathered, Corps managers "weigh and balance" potential impacts with project benefits, costs, and political considerations. This corresponds to the Risk Management process in the Risk Analysis paradigm. Because this step is often qualitative, Dr. Dillon said he prefers the term projection of environmental impacts rather than prediction, since the state of the art rarely justifies the latter. Field monitoring evaluates and validates the assessment.

Dr. Alavi explained that, as part of a Superfund project (Rocky Mountain Arsenal), the Army conducted an ecological risk assessment using a variation of the NAS paradigm. The assessment did not use a dose-response analysis, but rather an exposure pathway approach that assessed the exposure to all levels of the food chain to determine clean-up action levels. A different variation may be used at another site (Eagle River Flats) where a dose-response bioassay is underway with ducks that are dying from unknown effects on this heavy-artillary range in Alaska.

U.S. Fish and Wildlife Service. Dr. Gerould explained that the risk assessment method used by FWS depends on the question that needs to be answered, as well as the data that are available to carry out an assessment. FWS asks two questions at the outset of an assessment. What species are affected by the contamination? What cleanup level will be necessary to protect those species? Any assessment is difficult when few or no data are available, she added. Dr. Buckler listed the steps in the simplified risk assessment procedure used at FWS:

- Identify stressor (hazard identification).
- Identify organism(s) of concern.
- Determine sensitivity of organism to stressor (hazard evaluation).
- Determine or predict level of the organism(s)' exposure to the stressor (exposure assessment).
- Estimate probability of effect in organism(s) of concern at predicted or known level of exposure (risk characterization).

He added that this modified NAS paradigm works quite well for ecological risk assessment. Dr. Heinz agreed, stating that the dose-response assessment is very useful in predicting a problem and provides good evidence as to when there won't be a problem. This lessens the need for extrapolations, which lead to increased uncertainty.

National Oceanic and Atmospheric Administration. NOAA performs primarily effects assessments, by direct field measurement and laboratory tests, such as sediment bioassays.

U.S. Forest Service. The Forest Service uses a modified NAS risk assessment paradigm. Dr. Gross used an assessment of the risks from pesticides application as an example:

- Hazard analysis. The Forest Service gathers all available data on the pesticides from EPA and the open literature into a Background Statement. The Forest Service has compiled a list of pesticides for which Background Statements have been completed.
- Dose-Response assessment.
- Exposure assessment. In the case of pesticides, exposure will vary according to the application method used.
- Risk analysis. The risk to animals and humans is estimated.

Dr. Gross explained that the Forest Service can also provide a listing of Environmental Impact Statements (EISs) that include risk assessments.

U.S. Department of Energy. DOE uses the NAS paradigm for Superfund risk assessments. Parallel steps are used for both human health and ecological assessments.

How Do the Agencies Estimate Hazards to Organisms and Their Supporting Environment?

National Marine Fisheries Service. In the NMFS southeast region, the Beaufort Laboratory's staff, in conjunction with the NMFS Habitat Conservation Division, assesses environmental alterations through direct measurements and the use of process-oriented biological and chemical models. Examples of assessments include:

- Impacts of physical alterations on wetlands. (Nearly 90 percent of the Fisheries Service's work is in this area.)
- Impacts of electric power plants, including trace metals, thermal additions, and entrainment on streams and rivers.
- Effects of effluents from a copper smelter on estuarine species.
- Effects of water turbidity on sea grass survival.

U.S. Army. The Corps of Engineers identifies and estimates hazard in the initial phase of its assessment by thoroughly researching available literature and making observations in the field. Contaminant mobility and structure-function (as opposed to structure-activity) analyses are used to assess bioavailability, which contributes to the estimation of hazard.

U.S. Fish and Wildlife Service. Because FWS deals primarily with retrospective risk assessments and impact assessments, there is no need to estimate the hazard - it is already evident.

National Oceanic and Atmospheric Administration. NOAA's risk assessments are also primarily retrospective.

U.S. Forest Service. The Forest Service researches the existing literature to estimate hazard.

U.S. Department of Energy. DOE performs literature searches, and also takes on-site measurements to estimate hazard.

Discussion. Dr. van der Schalie asked if the Guidelines Work Groups had considered classifying ecological invasions as stressors in the risk assessment. Invasions may even be considered an effect on community diversity, he added. Some offices within EPA are working on some cases in the U.S. (e.g., zebra mussels in the Great Lakes), but EPA risk managers advised against dealing with that issue in this draft of the guidelines, explained Dr. Wood. The framework for incorporating new research will be in the first round of the ecological risk assessment guidelines, so ecological invasions may become a greater issue in later revisions.

How Do the Agencies Estimate or Monitor Exposure?

Food and Drug Administration. FDA considers cross-media exposures when modeling exposure to new materials. For example, a food additive may enter wastewater, but may be changed or eliminated in sewage treatment. It may partition to sewage sludge (in which case it is likely to ultimately constitute terrestrial exposure) or to the sewage effluent (where it becomes a source of exposure for aquatic species). All routes of environmental exposure are considered in estimating exposure. Often FDA has no data on the fate of the materials in waste treatment and discharge or land application; in these cases, FDA uses upper bound exposure estimates and available physiochemical data or structure-activity relationships.

U.S. Army. The Corps of Engineers considers both chemical and physical exposures in its exposure assessment. Because chemicals often bind to sediment, the overlying water is less contaminated; therefore, many organisms that do not come in contact with the bottom sediments are not exposed. The organisms' exposure in the water column is dependent on the chemicals' affinity for the sediment.

One participant asked whether the Corps assesses the exposure resulting from sediment disposal. That person was also interested in how the exposure changes with dredging, and whether piling the sediment in a confined landfill is actually better than leaving it spread on the bottom of the ocean, where the contaminants are more likely to be brought up through the food chain by bottom-dwellers. Dr. Dillon explained that no single disposal alternative was a panacea and because projects vary so greatly, each must be considered on its own merits. For example, upland disposal can have far greater environmental impacts than in-water relocation of dredged material. This is primarily because sediments oxidize under upland condition and contaminant mobility may increase dramatically. Runoff effluent, ground water and biota may all be affected. However, local communities may be willing to dispose in an upland environment and accept those risks in spite of the technical findings.

U.S. Fish and Wildlife Service. Dr. Heinz explained that FWS's exposure assessments are carried out by measuring contaminant levels in the organisms' food chain. He wondered why EPA does not consider determining harmful levels in food rather than in the water itself in the EPA Water Quality Criteria.

Dr. Buckler added that FWS is researching additional ways of assessing contaminant exposure. Analytical chemistry or bioassays alone have not drawn a complete picture of environmental exposure; analytical chemistry is costly and time-consuming, and the shift to less persistent chemicals reduces the value of residue data. A major thrust of FWS's current research is to combine the two techniques to assess exposure. They are looking for bioindicators (biomarkers) that would be better indicators of exposure. Dr. Whitworth asked if biomarkers were better indicators of exposure than of effect. Dr. Buckler responded that most biomarkers indicate exposure, but in some cases, it is not known whether that exposure leads to a significant effect. FWS is trying to gather funding for some additional work in this area, as there are probably many biochemical measures that can help assess exposure in the field.

How Do the Agencies Predict Population- and Community-Level Effects?

Food and Drug Administration. Although information regarding community-level effects is not required by FDA's regulations, FDA is interested in the ultimate effects of potential contaminants in the environment as a whole. FDA uses the "safety factor" approach with single species data to estimate a criterion concentration that is believed to be protective of populations. FDA funded research with microcosm projects by Dr. Robert Metcalfe (University of Illinois) and Dr. Frieda Taub (University of Washington) to develop test methods to directly measure community-level fate and effects. FDA would use micrososm or mesocosm test data in its review, if such data were available.

National Marine Fisheries Service. The Beaufort Laboratory is presently conducting research to determine how insults such as habitat alteration and direct and indirect chemical effects interact. Models using fishery statistics and ecological relationships have been developed to predict impacts from different types of stressors on fishery populations. These same types of models could be useful in estimating population effects due to chemical contamination.

U.S. Army. The Corps of Engineers measures mortality, growth and reproduction in appropriate sensitive test species. These results are used to project population- and community-level impacts. This is referred to as the "surrogate toxicological approach". Dr. Dillon stressed that ultimately, environmental impact assessment should address population and community effects; however, existing predictive tools at those levels of biological organization are not well developed. Consequently, most population/community level evaluations are retrospective and carried out in a monitoring mode. He indicated that research within the Corps of Engineers is exploring the use of demographic population models to express results of the "surrogate toxicological approach" in terms of population-level responses.

Fish and Wildlife Service. Dr. Heinz explained that FWS to date has depended on the protection of individuals to provide adequate protection for populations and communities. He wondered whether extrapolation to a whole population of a species is feasible given the current level of knowledge. FWS is looking at bioindicators of effect at various structural levels, from a change in water quality to individual- and population-level changes, to changes in community structure, and finally to effects at the ecosystem level. Dr. Buckler provided a list of indicators at each level that are being studied and developed at FWS (available from EPA; see Appendix H).

Dr. Buckler also said that FWS is using experimental ponds to assess how toxicity tests on individual species predict pond community function. Dr. Whitworth asked how well the toxicity tests work. He explained that, in one test, 96-hour LC50s and long-term tests of the juvenile lifestage were obtained using bluegills and compared to observed effects in experimental ponds. In general, the NOELs were comparable.

National Oceanic and Atmospheric Administration. NOAA is looking at ways to predict population response from mortality and reproduction data gathered in the field and laboratory, but has not been able to carry out the extrapolation as yet.

U.S. Forest Service. The Forest Service, as part of their land management mandate, must ensure that animal and plant populations present in an area prior to logging will return to their prior numbers within 5 years of clear-cutting. This puts the Service in a difficult position because preserving young tree and animal populations in the same area can often conflict. For example, herbicides meant to help softwood saplings compete with other plant species (vegetation control) can harm the animals, or animals can eat the saplings before they have a chance to grow. The Forest Service is in the process of deciding how to evaluate population viability and sensitivities of populations to the vegetation control regime.

Department of Energy. Dr. Bascietto explained that, under Superfund, no proof of population or community effects is needed, only adverse effect, period.

Discussion. Dr. Heinz asked if an extrapolation from individual to community effects would be a step forward for science, but a step back for regulations. It is much easier to regulate on the effects observed in an individual than to prove population- or community-level effects. One participant commented that extrapolation to population-level effects is not required by EPA's regulations (especially the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]), and in fact, the court has upheld the Office of Pesticides Program's stand that proof of population effects is not required to deny a pesticide registration. The requirement of proof does not come from regulations, but rather from the courts, he added.

Another attendee was concerned that little regulatory action is taken based on effects on individuals in the environment. The guidelines could provide a method for showing that the individual does matter (because the whole population is affected). Further, one could also argue that, in the regulations, health and welfare refers to effects on the individual, while protection of biological integrity refers to community-level effects.

Dr. Dorothy Patton, Executive Director of the RAF, stressed that the guidelines are for internal use, and if the work groups decide that population or community-level effects are important, then the guidelines should reflect that. It would be up to individual EPA offices whether to adopt that opinion. Dr. Gerould explained that, in the case of endangered species, an effect on even one individual is important in itself. At the same time, however, FWS may have to determine how much effect on the individual the population can bear.

Dr. Heinz again was concerned that EPA would back itself into a corner by asking for information on population-level effects. Will effects on the individual be considered unimportant from a regulatory standpoint a few years from now, when everyone forgets this discussion?

How Do the Agencies Choose and Measure Endpoints and Species of Concern for the Risk Assessment?

U.S. Food and Drug Administration. FDA considers a substance to be toxic if it is harmful to appropriate test organisms at expected environmental concentrations. Consequently, endpoints could include any suitable measure of harm to an appropriate test organism. Regulations require that the most sensitive endpoint obtained from acute or chronic tests must be used to determine the criterion concentration.

National Marine Fisheries Service. The research in the southeast is concerned with direct effects of stressors on recreationally and commercially important species and also indirect effects through damage to the food webs that support those species. When asked, Dr. Engel said that protected as well as threatened and endangered species, and recreationally and commercially important species are the focus of the protection effort.

Dr. Whitworth asked if Fisheries considers impacts on vegetated habitats the most sensitive endpoint, since most of the assessment described considered those habitats as being the most important. Dr. Engel explained that in his Division at the Beaufort Laboratory the research uses species abundance and diversity as endpoints to estimate the effects of habitat alteration. Pressed for his opinion of which stress poses the most important impact on commercial fisheries, he replied that probably sport and commercial fishing have the greatest impact. What makes ecological risk assessment so difficult is that all factors, i.e. habitat alteration and destruction, disease, coastal development, and contamination, overlap to affect both the habitat and the resident species.

U.S. Army. The primary endpoints assessed by the Corps of Engineers are survival, growth, and reproduction. These endpoints are chosen because:

- They are biologically and ecologically important endpoints.
- They are easily measured.
- Technical results are generally understood by the public, thus facilitating risk communication.

As Dr. Dillon described earlier, unacceptable adverse impacts are not allowed; EPA works with the Corps of Engineers to evaluate impacts using a tiered, effects-based approach.

Dr. van der Schalie stated that research is also being conducted at the Army Biomedical Research and Development Laboratory to explore the use of fish such as the medaka (*Oryzias latipes*) to evaluate the carcinogenic hazard of chemicals. Medaka were selected because of their small size, sensitivity to mammalian carcinogens, short tumor induction time, and relatively low testing costs. Medaka have been used in a mobile biomonitoring trailer to evaluate carcinogenic effects at hazardous waste sites. (Several other participants stated that they too have used the medaka for toxicity testing, and find it potentially useful for risk assessment.) The Army is also using the African clawed frog (*Xenopus laevis*) to assess developmental toxicity. In testing with known mammalian teratogens and non-teratogens, this system has had an overall accuracy rate of approximately 85 percent.

U.S. Fish and Wildlife Service. Dr. Gerould explained that, when the species of concern is not set by mandate from Congress, FWS chooses the endpoint or target species according to the following factors: economic and social importance; relationship to the test animal; and functional importance in the ecosystem. FWS's primary role is protection of natural resources and wildlife (mostly birds, but also some mammals, reptiles, and amphibians are studied).

To make recommendations for pesticide use near endangered species' habitat, FWS is developing a ranking risk assessment method that will prioritize species' response to pesticide exposure. Both direct and indirect effects will be assessed. The Service is using EPA's OPP Hazard Evaluation Procedure to determine the most sensitive habitats, symbionts, food organisms, and life stages.

U.S. Forest Service. The primary endpoint considered by the Forest Service is protection of all the plant, fish, and animal species within their managed lands, but especially endangered or socially important species. The assessment also considers pesticide effects on the health of the people who apply them.

A participant asked how unacceptable risk is determined. Dr. Gross explained that the decision-maker (risk manager) makes that determination. Often, risk to the worker who applies the pesticide is the deciding factor.

U.S. Department of Energy. The end product of DOE assessments at hazardous waste sites is a cleanup number that will minimize effects on human health and the environment. The Department intends to use Dr. Glenn Suter's assessment endpoint modeling scheme to choose target species at hazardous waste sites; his scenario involves identifying the environmental receptors of the contaminant. DOE also considers social and local importance.

One participant asked how DOE performs the risk assessment to protect a socially important species. If toxicity studies are conducted with earthworms, DOE won't argue to protect the worm? Dr. Bascietto explained that the most sensitive or appropriate species will drive the risk assessment, but the final risk management decision depends on social and economic factors.

How Do the Agencies Characterize Uncertainty in Their Assessments? Are the Results of the Assessment Qualitative or Quantitative?

U.S. Food and Drug Administration. As long as significant uncertainty remains in the assessment, FDA seeks further information, usually by asking the manufacturer or industry sponsor for additional testing. If significant uncertainty existed and no additional data would resolve the remaining uncertainty, FDA would prepare an environmental impact statement. The impact statement would identify alternative actions and mitigation measures, invite public involvement and comment, and describe the issues and uncertainties in detail. The final FDA decision would consider the environmental impacts (including uncertainties) and other relevant factors. FDA's assessment is qualitative in that it is used to determine if there is (or is not) significant impact.

National Marine Fisheries Service. Dr. Engel explained that NMFS uses a qualitative approach in most assessments, and the Fisheries will recommend against granting a permit if there is a reasonable probability of a measurable negative effect on fishery organisms. He also stated that this approach depends heavily upon professional judgement, and has worked thus far, even withstanding appeals in court. According to the existing system, the Habitat Conservation Division asks for a scientific opinion on a project, and depending upon the response, recommends denial or modification, or some other option to the Corps of Engineers. In the case of habitat alteration, NMFS can recommend action but does not have regulatory authority. In court actions, it is scientific judgement and credibility that is utilized.

A participant asked how NMFS defends its qualitative method in court. Dr. Engel replied that when valid scientifically based estimates of impact are presented, emotional or economically based arguments generally are negated. In Florida, for example, NMFS took field measurements and projected the impacts of the destruction of a mangrove stand on commercial and recreational fisheries. NMFS did not even quantify the percent reduction in fish populations, but since unacceptable damage was projected, the permit was denied, and the decision was upheld in Federal Appeals court.

Another participant asked if the possibility of mitigation influenced the decision to grant a permit. Others thought that such a risk management decision should not be considered in this discussion.

U.S. Army. The Army Biomedical Research and Development Laboratory has developed water quality criteria for the protection of aquatic life for Army-unique chemicals using EPA-recommended methodologies. In this respect, a quantitative approach has been used.

The Corps of Engineers conducts quantitative evaluative procedures. Uncertainty factors are used in some instances. However, Risk Characterization is qualitative and relies heavily on the use of best professional judgment.

U.S. Fish and Wildlife Service. FWS quantifies its assessment; however, Dr. Buckler said that there is no specific procedure, so professional judgement is relied upon. Dr. Heinz provided an example where successful natural nesting was characterized at different concentrations of selenium.

U.S. Forest Service. The Forest Service uses uncertainty factors in its assessments along with the lowest valid applicable (the endpoints' applicability to human effects is considered) NOEL or LC_{50}. The assessments are quantitative.

U.S. Department of Energy. DOE performs quantitative assessments that incorporate uncertainty factors.

Discussion. The participants who use quantitative risk assessment said that they use a cut-off point only - "if it exceeds this level, we'll see an effect."

Dr. Bascietto commented that, as more and more ecological factors are brought into the assessment, it becomes less and less quantitative. He wondered if the guidelines should propose quantitative risk assessments at this point. Dr. Gross stated that numbers in themselves do not mean anything in a risk assessment, it's how those numbers are interpreted. Dr. Whitworth explained that the guidelines may not help to produce quantitative numbers, but should help

The participants agreed that an uncertainty analysis is valuable for the risk manager, and that the guidelines should help the assessor identify the sources of uncertainty in the assessment. The assessor should not hide behind the number and rely on its indication of significant change to help the manager decide how to deal with the risk.

Are the Same Procedures Applied to Both Chemical and Physical Stressors?

National Marine Fisheries Service. Habitat modification and direct and indirect chemical effects are assessed through the use of ecosystem models, which are still under development.

U.S. Army. The Corps of Engineers assesses the same endpoints for both physical and chemical stresses. The response in the field detected by monitoring is the assessment's bottom line.

U.S. Fish and Wildlife Service. FWS, too, treats physical and chemical stressors similarly in the risk assessment.

U.S. Forest Service. Dr. Gross discussed primarily chemical impacts on the environment, although the Forest Service does assess impacts of recreational use and other physical alterations in Forest lands.

Dr. Whitworth commented that she would like to have a follow-up colloquium to discuss habitat alteration issues, so that physical stressors could be better addressed in the guidelines.

General Discussion

What Is the Role of Ecological Risk Assessment Guidelines and Ecological Risk Assessment in General?

There was some discussion concerning how the guidelines will be used, and whether the current paradigm works for ecological risk assessment. Dr. Whitworth stated that the guidelines should be useful to anyone who wants to perform ecological risk assessment, either prospective or retrospective. Will the current risk assessment scheme fit both cases?

Dr. Gerould thought that the paradigm works in either case, as long as enough ecological, toxicological, and exposure data is available. An altered NAS paradigm can be used to determine clean-up levels for hazardous waste sites; a prospective risk assessment can be used to choose among a group of remediation alternatives at a site.

Dr. Buckler was not aware of alternatives to the NAS paradigm, and an RAF member told the group that alternatives were suggested at the first RAF Ecological Risk Assessment Guidelines colloquium, most of which were variations on the existing scheme.

Some participants suggested that the guidelines set out a set of minimum standards that should be met in order to claim an ecological risk assessment has been performed for a stressor or at a site. This will be especially important since the guidelines will not necessarily be used exclusively by ecologists. The greatest benefit of setting out guidelines, stated one participant, is to minimize omissions in the assessment.

Should Post-Assessment Monitoring Be Recommended in the Guidelines?

Monitoring feedback into the risk assessment is a luxury not enjoyed by the human health risk assessors. Monitoring provides an opportunity to refine the assessment. There was some question, however, about whether monitoring should be set forth in the guidelines as a suggested step.

If new information reveals that a past action may significantly affect the environment, FDA has provisions for retroactive environmental review of prior actions. However, Dr. Harass stated that such retroactive consideration is very rare. The Army Corps of Engineers' monitoring activity varies from region to region, said Dr. Dillon. Most of the projections have been found to be reliable according to follow-up monitoring. The Department of Energy also conducts follow-up studies. The group thought that such a requirement may go beyond the definition of risk assessment, but also suggested that it be mentioned somewhere in the guidelines as a good idea. It will probably be a choice left up to the specific program offices at EPA.

Is Ecological Risk Assessment Feasible with Current Technology?

Dr. Heinz was concerned that, as population size gets larger, the extrapolation from individual to population will be more difficult. He stated that no consistently successful extrapolations from individual to whole community have been performed, and advised against relying upon such extrapolations because of the large uncertainties that would result.

Others pointed out the complexity of the ecological assessment and the many factors that drive the ecosystem's response to stress - from physical factors like soil erosion to the chemical interactions of mixtures in streams. Ecological variability is difficult to characterize. Even now, fish kills occur where researchers can detect no effect over background. Several participants doubted that an ecological risk assessment be able to take all of those factors into account. Some participants disagreed. In EPA's Pesticides Program, manufacturers can be asked to simulate any environment to prove that their pesticide has no unreasonable adverse effect on the environment. In assessing mixtures, many factors can be explained by specially developed models. Everyone acknowledged that predicting community effects would be harder, but stressed that the assessment would be more useful because all of those factors are taken into account.

A general consensus was reached: that EPA could attempt to produce the ecological risk assessment guidelines at one time, or over some years. The preferred option, however, would be to produce broad, general guidance that could be used as the basis of more detailed and specific guidelines.

ATTACHMENT A

Agenda, Speaker List

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

MEETING WITH FEDERAL REPRESENTATIVES

Washington Information Center
401 M Street, SW
Washington, DC 20460

May 14, 1990

Agenda

10:00am	Opening Remarks - William Wood, Risk Assessment Forum
10:20am	Issues for EcoRisk Guidelines - Guidelines Work Groups Aquatic Populations - Suzanne Marcy Terrestrial Populations - Anne Sergeant Aquatic Communities - Michael Brody
11:00am	Federal Agencies - Experiences and Perspectives
12:00pm	Lunch
1:00pm	Federal Agencies - Experiences and Perspectives (continuation)
3:00pm	Open Discussion
4:00pm	Conclusions
4:30pm	Adjourn

U.S. Environmental Protection Agency
RISK ASSESSMENT FORUM COLLOQUIUM

MEETING WITH FEDERAL REPRESENTATIVES

Invited Representatives

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APPENDIX G

U.S. Environmental Protection Agency
Science Advisory Board
Ecological Process and Effects Committee

Ecological Risk Consultative Group
May 7, 1990

Dr. Kenneth L. Dickson
Chairman
Ecological Process and
Effects Committee
Science Advisory Board

Dr. Edward S. Bender
Designated Federal Official
Ecological Processes and
Effects Committee
Science Advisory Board

INTRODUCTION

The Ecological Risk Consultative Group was convened at the request of the Risk Assessment Forum on May 7, 1990, to discuss several aspects of the scope of establishing ecological risk assessment guidelines and to provide a forum for an interactive discussion between the SAB and the Ecological Guideline work group chairs on technical issues in selected areas(see attachment A for list of questions). The consultation was used in this case as a means for a one time interaction with the ecological risk assessment guideline developers so that the SAB could provide input and suggests that could be considered in the development and scoping of the guidelines. The opinions are not intended to be committee consensus recommendations and unlike other SAB review, the results of this meeting will not result in a formal report to the Administrator nor will the SAB expect a formal response to the recommendations. The meeting room was set up in a collegial conference style that would promote the maximum degree of interaction.

The agenda (attachment B) was divided into two types of sessions. The morning session focused on broad questions dealing with the scope of ecological risk assessment guidelines. Drs. Patton and Slimak provided some introductory background which was intended to promote discussion. In the afternoon session, the Consultative Group focused on three broad areas of technical concern. For each topic, the discussion was lead initially by a member of the SAB, however the purpose of these sessions was to engage in questions and answers. During these sessions some questions and brief comments were taken from the audience as time permitted.

MEETING MINUTES

The meeting was called to order by the Chairman Dr. Kenneth Dickson at 10:40 a.m. The chairman explained the nature of the consultation as an interaction of the SAB and the Risk Assessment work group chairs and the organizing members of the RAF. The roster of the risk assessment consultative group are shown in the attached roster (attachment B). Missing from the meeting were Drs. Richard Kimerle, Dr. William Smith, Dr. Stanley Auerbach.

Dr. Donald Barnes, Director of the Science Advisory Board explained the nature of the consultation as a meeting at which the two groups interact. There is no formal response from the agency or the SAB.

Dorothy Patton, Director of the Risk Assessment Forum (R7F) provided an introduction to the RAF, its relationship to other parts of the agency. The Forum was developed in response to NAS recommendations that were established in the NAS "Red Book". The forum works on generic issues that are controversial and usually precedential. They work through three different types of groups: 1) uidelines work groups-these are long term, almost standing committees; 2) Technical Panels-usually put out special reports that supplement the work group efforts;and 3) Special members.

Dr. Patton said that EPA has learned a lot of lessons from developing risk assessment guidelines for careinogens. We must work to keep it simple, and state the scope and intent initially. The risk characterization needs to be developed more thoroughly than in the past. Policies need to be clearly identified.

Dr. Patton posed three questions to the SAB;

1) What would the SAB consider to be essential in the first draft?
2) What are some of the essential issues that should bee included in the first version of the guideline?
3) What should not be included?

General SAB Discussion

The Subcommittee members each expressed their views and questions related to Dr. Patton's questions. The Subcommittee discussed some needs for a first draft these included a need to focus on the purpose of the guidelines and to recogize natural variability. There was some discussion of the policy aspects of the guidelines and their relationship to risk mangement.

First we must accept that environments fluctuate.

Don Barnes-Purple book proposes to use equivalency.

Hirsch-Given the task and its complexity, we must plan and set up a mechanism to monitor the decisions and results that are determined using the proposed guideline so that the guideline can be conscientiously revised.

The guideline should describe the relationship between risk assessment and impact assessment and provide some rationale for choosing between the approaches.

One of the first steps is a cookbook. This is a role for Technical Support Documents.

There may be several paradigms that are linked to several different types of problems.

Another group member encouraged EPA to include both the bottom up and the top down approaches. Need to keep hazard and dose response approaches.

Mike Slimak, Deputy Director, OEPER

Overview of the practice of ecological risk:

Guidelines managers to be concerned with the decision and not the underlying science. There is a relationship between the stress and the ecological outcome as a result of that stress. Bottom up is factor (chemical) specific, and we are trying to establish the relationship between the stress and the type of effect (could be dose response effect).

Where do we start, top or bottom? Based on that choice of top-down, we formed three groups. There is presently guidance for the organism level.

Series of colloquia have been conducted during this spring, but these have been very helpful.

Other types of stressors could be included. Maybe risk assessment is not the appropriate mechanism.

SAB Discussion

The guidelines are the framework for the program specific guidelines.

They will cover all EPA uses.

The Subcommittee was divided on the need for statistical decision theory. Some said that statistical tools are not in place to handle uncertainty.

LUNCH 12:00

The SAB discussion on the quantitative nature of risk assessment continued after lunch.

Committee members noted the following:

There are quantitative ways of dealing with qualitative data. The pathology example is an ordinal one.

Risk assessment has some relationship to quantification. Even the present methods that are available include quantity, so it is hard to envision a qualitative risk assessment.

EPA must separate risk assessment from risk management, but the qualitative approach requires risk management to make the decision rules. The lack of separation is a problem.

Predictive risk assessment needs to be somewhat flexible.

EPA need to control bias, understand dispersion, and the ability to detect type 1 and 2 errors. There is no clear cut presumption of whether we are trying to design a system that is

over or under protective. We need objective answers as to the actual or predicted risks. When you mix the management and science you cannot be sure that how the result is biased.
For uncertainty- Does the science exist to statistically assess uncertainty?

Do we need to understand the ecological processes better than we currently can, in order to perform a risk assessment?
This is what we know and this is how we know it.

It is Advisable to develop guidelines, because it reveals the state of the science.

However, we must recognize that the guideline is an evolutionary process, that will meet a current need and more specifics can be added later.

Endpoint Selection

Dr. Hirsch-Introduction

This is the greatest difference between the human health and ecological risk assessment. The endpoints may relate to socially or scientifically desireable goals. They may relate to adverse effects.

Production of a valued species is easy. What about other measures, such as population size?

The problem is in the interpretation, because of the stochastic (variability of the environment). In an ideal situation, you would want to get a dose response relationship. You get many correlations, but you need causation.

Are there any critical issues for the agency? The agency has not made any specific statements.

Community measures that would be recommended.

-Concern for endangered species.
-Biodiversity is filled with problems that are often related to particular index used.

Let the program recommend endpoints and let the risk forum develop indicators for endpoints which are not conveniently measured.

Start with legislation as a basis for endpoints (this is the first step). You can come up with a suite of endpoints that are generic. This has some value. It is difficult to take the next step, because we don't know the natural variability.

The Subcommittee agreed that this effort needs coordination with EMAP.

Suzanne Marcy-Aquatic Populations-endpoints

We are using the research available to go from the bottom up, but we are so accustomed to working with single species that we forget about the exposures and effects on the prey, predators and other competitors which have different exposures. This is not currently predictable. Therefore the sum of the parts does not allow extrapolation to the community level of organization.

If we are concerned about diversity what should we measure? Don't rely on it to be sensitive. The population is a relative risk assessment and therefore the assessment of populations is site specific. Ecorisk assessment is not a stand alone management tool.

Risk assessment is an instrument for answering questions that are posed. Endpoints are the risk of what (something happening), where what is the endpoint. Perhaps enter into an interagency agreements with the various source management agencies.

Aquatic communities-endpoints
Mike Brody, So far they have not focused on endpoints. What can we learn about the potential or actual impacts by looking at mesocosms, ponds, etc.? What are the warning indications of community impacts? For example, Schnidler's shifts in phytoplankton species appears to be the most sensitive. May want to look at keystone, sentinel or what ever population that may tend to structure the community. This is primarily related to field measurements. The group is looking at potential data sets. General advice of the Experts from our Colloquia was that the agency was not ready for functional measurements.

Currently the Agency work group has not found a theoretical background to fit the risk paradigm. Indicator species are probably not very important.

Quantifying Uncertainty

We are still uncomfortable about the idea of uncertainty. A risk assessment is necessarily quantitative. There is nothing magical about the risk assessment process at all. It is just a book keeping exercise. If we take all the information we have, we can use a cumulative frequency distribution and its related range of uncertainty. This gives the decision maker the opportunity to see the risk and the potential for error. What new data can I gather to change the inputs to the risk assessment so I can get a better handle on the risk and reduce uncertainty.

In many areas the risk is very difficult to define. We may not know what the shape of the model is. It may even overwhelm the other aspects or data of the system.

Perhaps, we must find different ways to communicate this uncertainty to the manager. The reasons for uncertainty are both natural and man-made. In terms of communicating uncertainty, the best thing the risk analyst can present is the risk distribution curve.

How do you add exposure to the cumulative frequency curve? These are used with a batesian statistic, each parameter has its own distribution which can be done mathematically or by Monte Carlo simulation. The problem is that the scenario and the analytical chemistry do not provide information on the availability.

If you have QA/QC pedigrees you can construct these curves. If no information is available, then you can guess, but its possible. The problem is that the risk of different events is perceived differently by the public depending upon the nature of the problem.

The complexity of the data requirements may overwhelm the preparer of the risk assessment.

What are the preferred approaches for extrapolation between species and communities? Dr. Glen Suter (Oak Ridge National Laboratory) has used the empirical approach and the human to rat extrapolation was done mechanistically.

RISK CHARACTERIZATION

Dr. Dickson-Introduction

There was some argument about how risk characterization is related to risk communication. Do you include these together?

Distinguish between the development and the use of the risk assessment. There is a distinction in health area. What is the background variability and experience of the specific ecosystems when they are stressed so that the risk assessment manager can understand what is the significance of the estimated risk.

Don't take this as a hypothesis testing approach. Instead take a parameter measurement approach because it doesn't have an inherent bias and it is not subject to being gerrymandered.

Most concerned with explaining what the predicted effect might mean to the population, to the community, or to the ecosystem? Are these effects additive or less?

There ought to be a list of questions or a checklist that a manager should ask about each risk assessment he receives.

CONCLUSIONS

1. The SAB did not get settled in their minds what questions might be proposed as part of the public notice for ecological risk assessment guidelines.

2. Risk assessment methodologies for populations, and communities will be a very big effort. These guidelines should include quantitative and qualitative examples.

3. Need to include state of the art statistical theory.

4. Need to consider ecosystem models.

5. Set aside ecosystems for this time.

6. Community framework is still missing. Need to see if the existing theory can fit into the assessment methodology. Concepts of resiliency and stability.

7. It may well be that the variability from all sources of measurement, exposure, and effects is so great that it would be impractical to assess ecorisk, but by the time you realize it you may have so much energy invested that you may be unavoidably committed.

The meeting was adjourned at 4:45 p.m.

Attachment A

Ecological Risk Assessment Consultation Group
From Dorothy Patton and Bill Wood

We expect the May 7 consultation to be an exchange of ideas and questions between SAB members and the chairpersons for the EPA Work Groups responsible for the Guidelines. EPA will open the meeting with a brief overview of the current guideline development plan, detailed in the attached outlines. The Agency is interested in SAB views on the scope and content of the guidelines. In particular, we are interested in three general questions:

1) What information, principles, and methods are essential to be included in the guidelines at this time?
2) What controversial issues, though unsettled and perhaps unlikely to be fully resolved, should be addressed in some way?
3) What controversial issues that, though important, can reasonably be put aside at the present time?

SCIENTIFIC ISSUES

In discussions within the Agency and with other scientists, several fundamental scientific issues seem critical to the development of these guidelines.

I. Endpoint Selection

One dilemma of ecological risk assessment is the large array of possible endpoints and indicators of stress that can be the focus of an assessment. How should one select from this array? What principles and or criteria can be articulated which could guide the assessor in this selection? For example, should endpoint selection be based solely on ecological significance, or be limited to concerns that the risk manager can easily appreciate, or be limited to environmental characteristics that are easily measured?

II. Uncertainty Issues

What are the preferred approaches for dealing with extrapolations from species to species, laboratory to field conditions, time period to time period (e.g., acute to chronic), endpoint to endpoint (e.g., LC50 to LOEL or NOEL), and to other levels of organization?

III. Risk Characterization

It is generally felt by those involved in the guidelines development that more will need to be done in these guidelines than the health guidelines in trying to bridge the gap between risk assessment and risk management. To what extent should these guidelines address the "so what" issues? For example, should the guidelines address the significance of specific levels of population reduction? How should natural variability in population levels and recovery be dealt with?

Attachment D

FINAL AGENDA 5/2/90
U.S. ENVIRONMENTAL PROTECTION AGENCY
ECOLOGICAL PROCESSES AND EFFECTS COMMITTEE
ECOLOGICAL RISK CONSULTATIVE GROUP

Dominion Room 1
Howard Johnson Hotel
2650 Jefferson Davis Highway
Arlington, VA 22202

Monday, May 7, 1990

10:30 a.m.	Call to Order (Ken Dickson, Chairman) a. Purpose of Consultation b. Introduction of Group Members c. Administrative moment (Ed Bender, DFO and Frances Dolby, Committee Secretary)
10:45 a.m.	The Guidelines Development Process and Issues (Dorothy Patton, Director, Risk Assessment Forum) Functional relationship of the Forum, the RAC, & the Eco-oversight Group
11:00 a.m.	Discussion with SAB Committee
11:30 a.m.	The practice of ecological risk: an overview (Mike Slimak, Leader Ecol. Guideline Workgroup)
12:00 p.m.	Discussion (K. Dickson) Opportunity for Public Comment
12:30 p.m.	LUNCH

(Afternoon will be a discussion of several substantive areas of risk assessment. A member of the SAB consultative work group will lead the discussion which will be an interaction between the SAB and the EPA Ecological Risk Guideline Work Group.)

1:30 p.m.	Endpoint Selection
2:30 p.m.	Uncertainty Issues
3:30 p.m.	Risk Characterization
4:30 p.m.	Adjourn

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APPENDIX H

REFERENCES

NOTE: References marked with an asterix (*) are available from the EPA Headquarters Library, Public Reference Unit, 401 M Street, SW, Washington, DC 20460.

The National Academy of Sciences Risk Assessment Paradigm

Basciettto, J., D. Hinckley, J. Plafkin, and M. Slimak. 1990. Ecotoxicity and ecological risk assessment: regulatory applications at EPA. (First of a four-part series). Environ. Sci. Technol. 24(1):10-15.

National Research Council. 1983. The nature of risk assessment. In: Risk assessment in the federal government: managing the process. Washington, DC: National Academy Press, pp. 17-50.

*Society of Environmental Toxicology and Chemistry. 1987. Draft Report: Research priorities in environmental risk assessment. J.A. Fava, W.J. Adams, R.J. Larson, G.W. Dickson, K.L. Dickson, and W.E. Bishop, Eds. Breckenridge, CO.

Suter, G.W. 1989. Chapter 2, Ecological endpoints. In: U.S. Environmental Protection Agency. Ecological assessment of hazardous waste sites: a field and laboratory reference. EPA/600/3-89-013. Corvallis, OR: U.S. EPA Environmental Research Laboratory, pp. 2-1 to 2-28.

*Also hard copies of visual materials and/or handouts from the following speakers:

Dr. Lawrence Barnthouse
Dr. Mark Harwell
Dr. Glenn Suter

Uncertainty Issues in Hazard Assessment

Hoffman, D.J., B.A. Rattner, R.J. Hall. 1990. Wildlife toxicology (Third of a four-part series). Environ. Sci. Technol.

Mayer, F.L., K.L. Mayer, M.R. Ellersieck. 1986. Relation of survival to other endpoints in chronic toxicity tests with fish. Environ. Toxicol. Chem. 5:737-748.

Suter, G.W., D. S. Vaughn, and R.H. Gardner. 1983. Risk assessment by analysis of extrapolation error: a demonstration for effects of pollutants on fish. Environ. Toxicol. Chem. 2:369-378.

*Also hard copies of visual materials and/or handouts from the following speakers:

- Dr. Steve Bradbury
- Dr. Glenn Suter
- Dr. Ron Preston
- Dr. Lorenz Rhomberg

Uncertainty Issues in Exposure Assessment

*Lower, W.R. and R.J. [illegible]all. University of Missouri Environmental Trace Substances Research Laboratory, Clemson University Institute of Wildlife and Environmental Toxicology. 1990. Sentinel species and sentinel bioassay. Unpublished paper. Columbia, MO: University of Missouri.

Niemi, G.J., P. DeVore, N. Detenbeck, D. Taylor, J.D. Yount, A. Lima, J. Pastor, and R. J. Naiman. 1990. An overview of case studies on recovery of aquatic systems from disturbance. Environmental Management, Vol. 14, No. 5. New York, NY: Springer-Verlag. In press.

*Yount, J.D. and G.J. Niemi, Eds. 1990. Recovery of lotic communities and ecosystems following disturbance - a narrative review of case studies. Environmental Management, Vol. 14, No. 5. New York, NY: Springer-Verlag. In press.

Yount, J.D. U.S. Environmental Protection Agency. 1989. Analysis of criteria exceedences as related to aquatic community impact. Unpublished paper. ERL-Duluth Milestone no. 6964A. Duluth, MN: U.S. Environmental Protection Agency Environmental Research Laboratory.

*Also hard copies of visual materials and/or handouts from the following speakers:

- Dr. Louis Best
- Dr. William Lower
- Dr. Frieda Taub

Population Modeling

Barnthouse, L.W., G.W. Suter, and A.E. Rosen. 1990. Risks of toxic contaminants to exploited fish populations: influence of life history, data uncertainty and exploitation intensity. Environ. Toxicol. Chem. 9:297-311.

Caswell, H. 1989. Analysis of life table response experiments - decomposition of effects on population growth rate. Ecol. Modeling. 46:221-237.

Fogarty, M.J. 1989. Forcasting yield and abundance of exploited invertebrates. In: Caddy, J.F., ed. Marine invertebrate fisheries: their assessment and management. New York, NY: John Wiley and Sons, Inc., pp. 701-724.

Ginzberg, L.R., S. Ferson, H.R. Akcakaya. 1990. Reconstructibility of density dependence and the conservative assessemnt of extinction risks. Conservation Biology. 4(1):63-70.

Weinberg, J.R. 1985. Factors regulating population dynamics of the marine bivalve *Gema gema*: Intraspecific competition and salinity. Marine Biology. 86:173-182.

*Also hard copies of visual materials and/or handouts from the following speakers:

Dr. James Weinberg
Dr. Michael Fogarty
Dr. Lev Ginzburg
Dr. Lawrence Barnthouse

Meeting with State Representatives

*Beaumier, R.B. and Dudley, D. 1987. Water Quality Based Effluent Limits (WQBEL) for Ranco, Inc. Memorandum to M. Tinn, Chief, DWPC. Columbus, OH: Ohio Environmental Protection Agency, Division of Water Quality Management and Assessment. May 29.

*ENSR Consulting and Engineering. 1989. Risk Assessment Report: UOP Superfund Site, East Rutherford, NJ, Vol. II. Morristown, NJ: Allied-Signal, Inc.

*Michigan Department of Natural Resources. 1985. Guidelines for Rule 57(2). Lansing, MI: Michigan Department of Natural Resources.

*Michigan Department of Natural Resources. 1984. Staff Report: Support Document for the Proposed Rule 57 Package. Lansing, MI: Michigan Department of Natural Resources, Environmental Protection Bureau.

*Michigan Department of Natural Resources. 1986. Water Resources Commission General Rules. Lansing, MI: Michigan Department of Natural Resources.
Ohio Environmental Protection Agency. 1989. Policy for Implementing Chemical Specific Water Quality Based Effluent Limits and Whole Effluent Toxicity Controls in NPDES Permits. Columbus, OH: Ohio Environmental Protection Agency.

*Ohio Environmental Protection Agency. 1990. State of Ohio Water Quality Standards, Chapter 3745-1 of the Administrative Code. Columbus, OH: Ohio Environmental Protection Agency, Division of Water Quality Planning and Assessment.

*Ohio Environmental Protection Agency. 1988. Water Quality Based Effluent Limits Report, The Timken Company. Columbus, OH: Ohio Environmental Protection Agency, Division of Water Quality Planning and Assessment.

*O'Toole, M. and Wich, K. 1989. Division Technical and Administrative Guidance: Habitat based assessment guidance document for conducting environmental risk assessments at hazardous waste sites. Memorandum to Regional Hazardous Waste Engineers, Bureau Directors, Section Heads, and Regional Supervisors of Natural Resources. Albany, NY: Bureau of Environmental Protection, Division of Fish and Wildlife. December 28.

*PTI Environmental Services. 1990. Sediment Ranking System. Bellevue, WA: PTI Environmental Services. Ecology Contract no. C0089008. Washington Department of Ecology.

*Resource Planning Associates (prepared by Tetra Tech, Inc.). 1986. A Framework for Comparative Risk Analysis of Dredged Material Disposal Options. Bellevue, WA: Tetra Tech, Inc. U.S. Army Corps of Engineers.

*Stansbury, J., I. Bogardi, and W.E. Kelly. University of Nebraska - Lincoln. 1990. Risk-Cost Analysis for Dredged Material Disposal. Project Design Summary. Lincoln, Nebraska: University of Nebraska, Department of Civil Engineering. Prepared for: U.S. Army Corps of Engineers, Institute for Water Resources, Fort Belvoir, VA.

Sullivan, J.R., T.J. Kubiak, T.E. Amundson, R.E. Martini, L.J. Olson, and G.A. Hill. 1988. A Wildlife Exposure Assessment for Landspread Sludges Which Contain Dioxins and Furans. Tenth Annual Madison Waste Conference - Municipal and Industrial Waste. Madison, WI: University of Wisconsin, Department of Engineering Professional Development, pp. 406-415.

U.S. Environmental Protection Agency, Region 10 (prepared by PTI Environmental Services). 1988. The Apparent Effects Threshold Approach. Briefing Report to the EPA Science Advisory Board. Seattle, Washington: U.S. EPA, Region 10, Puget Sound Estuary Program. EPA Contract no. 68-03-3534.

U.S. Environmental Protection Agency. 1987. The Risk Assessment Guidelines of 1986. EPA/600/8-87-045. Washington, DC: U.S. Environmental Protection Agency.

*Also hard copies of visual materials and/or handouts from the following speakers:

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